Kuraray Noritake Dental Inc.
Yasujiro Ohara
General Manager
Tokiwabashi Tower, 2-6-4, Otemachi
Chiyoda-ku, Tokyo 100-0004
JAPAN

May 24, 2024

Re: K233285
Trade/Device Name: KATANA Zirconia ONE For IMPLANT
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA, PNP
Dated: April 26, 2024
Received: April 26, 2024

Dear Yasujiro Ohara:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Andrew I. Steen -S

Andrew I. Steen
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K233285

Device Name
KATANA Zirconia ONE For IMPLANT

Indications for Use *(Describe)*

KATANA Zirconia ONE For IMPLANT is intended for use in partially or fully edentulous mandibles and maxillae in support of single cement-retained restorations.

For the SBL 3.3 L titanium bases, the indication is restricted to the replacement of single lateral incisors in the maxilla and lateral and central incisors in the mandible.

KATANA Zirconia ONE For IMPLANT is used in combination with the TiBase and Sirona Dental CAD/CAM System. KATANA Zirconia ONE For IMPLANT cemented to the TiBase is recommended for two-piece hybrid abutments for single tooth restorations and hybrid abutment crowns, used in conjunction with endosseous dental implants.

Compatible implant systems and TiBase are as follows.

Implant system (Manufacturer)	Platform	Sirona TiBase	
		Name	Size
Replace, Replace Select (Nobel Biocare)	NP	TiBase NB RS 3.5 L	L
	RP	TiBase NB RS 4.3 L	
	WP	TiBase NB RS 5.0 L	
	6.0	TiBase NB RS 6.0 L	
Nobel Active NobelReplace Conical Connection (Nobel Biocare)	NP	TiBase NB A 4.5 L	L
	RP	TiBase NB A 5.0 L	
Bone Level (Straumann)	NC (3.3 mm)	TiBase S BL 3.3 L	L
	RC (4.1 mm / 4.8 mm)	TiBase S BL 4.1 L	
Certain (Biomet 3i)	3.4	TiBase B C 3.4 S	S
	4.1	TiBase B C 4.1 L	L
	5.0	TiBase B C 5.0 L	
Tapered Screw-Vent (Zimmer)	3.5	TiBase Z TSV 3.5 L	L
	4.5	TiBase Z TSV 4.5 L	
	5.7	TiBase Z TSV 5.7 L	

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Date: 24th May 2024

510(k) Summary

1. 510(k) owner (submitter)

1) Name	Kuraray Noritake Dental Inc.
2) Address	1621 Sakazu, Kurashiki, Okayama 710-0801, Japan
3) Contact person	Yasujiro Ohara General Manager Quality Assurance Department
4) Contact person in US	Manabu Suzuki Director KURARAY AMERICA, INC. 32 Old Slip, 7th Floor, New York, NY 10005 Tel: (212)-986-2230 (Ext. 115) or (800)-879-1676 Fax: (212)-867-3543

2. Name of Device

1) Trade / Proprietary name	KATANA Zirconia ONE For IMPLANT
2) CFR Number	21 CFR 872.3630
3) Device Class	Class II
4) Product code	
・Primary Product code	NHA (Abutment, Implant, Dental, Endosseous)
・Secondary Product code	PNP (Dental Abutment Design Software for Dental Laboratory)
5) Panel	Dental

3. Predicate and Reference devices

3-1. Primary predicate device

1) Trade / Proprietary name	Sirona Dental CAD/CAM System with CEREC Chairside software
2) 510(k) number	K193408
3) Classification name	Abutment, Implant, Dental, Endosseous (21 CFR section 872.3630. Product code: NHA) Dental Abutment Design Software For Dental Laboratory (21 CFR section 872.3630. Product code: PNP)
4) Applicant name	Dentsply Sirona

3-2. Reference devices

Reference device 1

1) Trade / Proprietary name	Sirona Dental CAD/CAM System with InLab Software
2) 510(k) number	K200191
3) Classification name	Dental Abutment Design Software For Dental Laboratory (21 CFR section 872.3630. Product code: PNP)
4) Applicant name	Dentsply Sirona

Reference device 2

1) Trade / Proprietary name	KATANA Zirconia Block
2) 510(k) number	K190436
3) Classification name	Powder, Porcelain (21 CFR section 872.6660. Product code: EIH)
4) Applicant name	Kuraray Noritake Dental Inc.

Reference device 3

1) Trade / Proprietary name	IPS e.max CAD Abutment Solutions- extra systems
2) 510(k) number	K191382

3) Classification name	Abutment, Implant, Dental, Endosseous (21 CFR section 872.3630. Product code: NHA)
4) Applicant name	Ivoclar Vivadent, AG

Reference device 4

1) Trade / Proprietary name	PANAVIA SA Cement Universal
2) 510(k) number	K183537
3) Classification name	Cement, Dental/Agent, Tooth Bonding, Resin (21 CFR section 872.3275/872.3200. Product code: EMA/KLE)
4) Applicant name	Kuraray Noritake Dental Inc.

Reference device 5

1) Trade / Proprietary name	Sirona Dental CAD/CAM System
2) 510(k) number	K181520
3) Classification name	abutment, implant, dental, endosseous (21 CFR section 872.3630. Product code: NHA)
4) Applicant name	Dentsply Sirona

4. Device Description

The KATANA Zirconia ONE For IMPLANT mesostructure material (conforming to ISO 6872:2015) is a pre-sintered zirconia block to be used as the ceramic mesostructure component of a two-piece titanium base abutment. KATANA Zirconia ONE For IMPLANT is compatible with the specified TiBase and the CAD/CAM component of the Sirona Dental CAD/CAM system (K193408, K200191) as identified in the Indications for Use. This device is further processed by the trained professional to make individually designed mesostructure that are milled into the desired shape of a hybrid abutment or hybrid abutment crown.

The Zirconia block has identical chemical composition as our own previously cleared reference device, KATANA Zirconia Block (K190436) under product code "EIH".

The mesostructure material of KATANA Zirconia ONE For IMPLANT is available in shades, A1, A2, A3, A3.5, B1, B2, C1, C2, D2 and NW for flexibility and application variety to meet individual patient needs. The mesostructure material of KATANA Zirconia ONE For IMPLANT is available with one block size and two sizes of access hole, which is small (S) and large (L).

The abutment must be sterilized after the cementation of the CAD/CAM patient matched mesostructure on the pre-manufactured titanium base component. PANAVIA SA Cement Universal (K183537) is used as the cement to set the mesostructure material to TiBase when the mesostructure material of the subject device set to TiBase prior to sterilization.

Dentsply Sirona has issued a letter of authorization indicating that the subject mesostructure material of the subject device can be selected in combination with the CAD/CAM system. Kuraray Noritake Dental and Dentsply Sirona have a business agreement for adding this new material to the Sirona CAD/CAM system. Kuraray Noritake Dental has worked with Dentsply Sirona to implement their new material into the Sirona CAD/CAM system libraries.

KATANA Zirconia ONE For IMPLANT which is the subject of this premarket notification consists of:

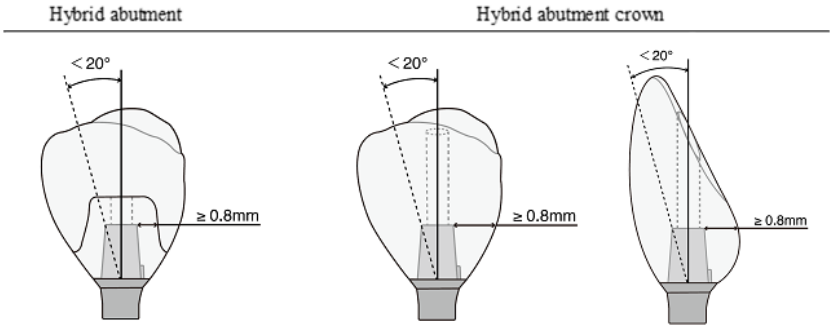
- Sirona Dental CAD/CAM System with CEREC Chairside Software or with inLab Software
- Sirona TiBase
- KATANA Zirconia ONE mesostructured blocks

Compatible titanium bases are shown in below table.

Table 4: Compatibility of intended Sirona TiBase with KATANA Zirconia ONE For IMPLANT

Ti Base			Compatible System			
Name	Dentsply Sirona Ref	Interface size	Manufacturer/ Line		Platform	Diameter
TiBase NB RS 3.5 L	6282474	L	Nobel Biocare	Replace, Replace Select	NP	3.5
TiBase NB RS 4.3 L	6282482	L			RP	4.3
TiBase NB RS 5.0 L	6282490	L			WP	5.0
TiBase NB RS 6.0 L	6282508	L			6.0	6.0
TiBase NB A 4.5 L	6308188	L		Nobel Active, NobelReplace Conical Connection	NP	3.5
TiBase NB A 5.0 L	6308253	L			RP	4.3/5.0
TiBase S BL 3.3 L	6308154	L	Straumann	Bone Level	NC	3.3
TiBase S BL 4.1 L	6308337	L			RC	4.1/4.8
TiBase BC 3.4 S	6308048	S	Biomet 3i	Certain	3.4	3.4
TiBase B C 4.1 L	6308097	L			4.1	4.1
TiBase B C 5.0 L	6308121	L			5.0	5.0
TiBase Z TSV 3.5 L	6282581	L	Zimmer	Tapered Screw-Vent	3.5	3.7/4.1
TiBase Z TSV 4.5 L	6282599	L			4.5	4.7
TiBase Z TSV 5.7 L	6282607	L			5.7	6

The subject device is procced within the following design parameter range.



OR

The minimum wall thickness of the restoration must be 0.8 mm.

The parameters of this product for fabricating prosthetics are as following:

Item	Parameter	Remark
a) Abutment post height*1	4.0 mm ~ 16.7 mm	Minimum value is followed by FDA's recommendation. Maximum value set by considering product's dimension and shrinkage of block.
b) Angulation	0° ~ 20°	Angulation over 20° is contraindication at TiBase.
c) Wall thickness	0.8 mm ~ 9.5 mm	Range of wall thickness is limited by allowance of access hole, the dimensions and shrinkage of block.
d) Diameter	3.3 mm ~ 6.0 mm*2	This value set by Dentsply Sirona. It was confirmed that the mesostructure of subject device could applied within those range of diameter.
e) Gingival height	1.0 mm*2	This value set by Dentsply Sirona.

*1 The abutment post height is considered by FDA to be the "stump" portion above the gingival collar, to which the restorations attach.

*2 Parameters of diameter and gingival height are depended on a selected TiBase.

5. Substantial Equivalence Discussion

5-1. Indications for Use / Intended Use

It is described that the indications for use of the subject device set as followings:

KATANA Zirconia ONE For IMPLANT is intended for use in partially or fully edentulous mandibles and maxillae in support of single cement-retained restorations.

For the SBL 3.3 L titanium bases, the indication is restricted to the replacement of single lateral incisors in the maxilla and lateral and central incisors in the mandible.

KATANA Zirconia ONE For IMPLANT is used in conjunction with TiBase and Sirona Dental CAD/CAM System. KATANA Zirconia ONE For IMPLANT cemented to the TiBase is recommended for two-piece hybrid abutments for single tooth restorations and hybrid abutment crowns, used in conjunction with endosseous dental implants.

Compatible implant systems and TiBase are as follows:

Implant system (Manufacturer)	Platform	Sirona TiBase	
		Name	Size
Replace, Replace Select (Nobel Biocare)	NP	TiBase NB RS 3.5 L	L
	RP	TiBase NB RS 4.3 L	
	WP	TiBase NB RS 5.0 L	
	6.0	TiBase NB RS 6.0 L	
Nobel Active NobelReplace Conical Connection (Nobel Biocare)	NP	TiBase NB A 4.5 L	L
	RP	TiBase NB A 5.0 L	
Bone Level (Straumann)	NC (3.3 mm)	TiBase S BL 3.3 L	L
	RC (4.1 mm / 4.8 mm)	TiBase S BL 4.1 L	
Certain (Biomet 3i)	3.4	TiBase B C 3.4 S	S
	4.1	TiBase B C 4.1 L	L
	5.0	TiBase B C 5.0 L	
Tapered Screw-Vent (Zimmer)	3.5	TiBase Z TSV 3.5 L	L
	4.5	TiBase Z TSV 4.5 L	
	5.7	TiBase Z TSV 5.7 L	

This Indications for Use is substantially equivalence to the reference device (IPS e.max CAD Abutment Solutions- extra systems, K191382) / the predicate device (Sirona Dental CAD/CAM System with CEREC Chairside software (K193408)) / the reference device (Sirona Dental CAD/CAM System (K181520)). It is the description as follows that we conducted the comparison between the subject device and the reference device.

Subject device: KATANA Zirconia ONE For IMPLANT	Primary predicate device: Sirona Dental CAD/CAM System with CEREC Chairside software (K193408)	Reference device: Sirona Dental CAD/CAM System (K181520)	Reference device: IPS e.max CAD Abutment Solutions- extra systems (K191382)
KATANA Zirconia ONE For IMPLANT is intended for use in partially or fully edentulous mandibles and maxillae in support of single cement-retained restorations. For the SBL 3.3 L titanium bases, the indication is restricted to the replacement of single lateral incisors in the maxilla and lateral and central incisors in the mandible. KATANA Zirconia ONE For IMPLANT is used in combination with the TiBase and Sirona Dental CAD/CAM System. KATANA Zirconia ONE For IMPLANT cemented to the TiBase is recommended for two-piece hybrid abutments for single tooth restorations and hybrid abutment crowns, used in conjunction with endosseous dental implants.	The Sirona Dental CAD/CAM System with CEREC Chairside Software is intended for use in partially or fully edentulous mandibles and maxillae in support of single or multiple-unit cement retained restorations. For the AT TX 3.0 S, BH 3.0 S, SSO 3.5 L, and SBL 3.3 L titanium bases, the indication is restricted to the replacement of single lateral incisors in the maxilla and lateral and central incisors in the mandible. The system consists of three major parts: TiBase, inCoris mesostructure and CAD/CAM software. Specifically, the inCoris mesostructure and TiBase components make up a two- piece abutment which is used in conjunction with endosseous dental implants to restore the function and aesthetics in the oral cavity. The inCoris mesostructure may also be used in conjunction with the Camlog Titanium base CAD/CAM (types K2244.XXXX) (K083496) in the Camlog Implant System. The CAD/CAM software is intended to design and fabricate the inCoris mesostructure.	The Sirona Dental CAD/CAM System is intended for use in partially or fully edentulous mandibles and maxillae in support of single or multiple-unit cement retained restorations. For the BH 3.0 S, SSO 3.5 L and S%L 3.3 L titanium bases, the indication is restricted to the replacement of single lateral incisors in the maxilla and lateral and central incisors in the mandible. The system consists of three major parts: TiBase, inCoris mesostructure, and CAD/CAM software. Specifically, the inCoris mesostructure and TiBase components make up a two-piece abutment which is used in conjunction with endosseous dental implants to restore the function and aesthetics in the oral cavity. The inCoris mesostructure may also be used in conjunction with the Camlog Titanium base CAD/CAM (types K2244.XXXX) (K083496) in the Camlog Implant System. The CAD/CAM software is intended to design and fabricate the inCoris mesostructure.	IPS e.max CAD Abutment Solutions is intended for use in partially or fully edentulous mandibles and maxillae in support of single cement-retained restorations. The system comprises three parts: - IPS e.max CAD ceramic structure - Ti base - CAD/CAM system. The IPS e.max CAD ceramic structure cemented to the Ti base is recommended for two-piece hybrid abutments for single tooth restorations and hybrid abutment crowns, used in conjunction with endosseous dental implants.

<table>
<tr>
<td>Subject device:
KATANA Zirconia ONE For IMPLANT</td>
<td>Primary predicate device:
Sirona Dental CAD/CAM System with CEREC Chairside software (K193408)</td>
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Sirona Dental CAD/CAM System (K181520)</td>
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IPS e.max CAD Abutment Solutions- extra systems (K191382)</td>
</tr>
<tr>
<td>Compatible implant systems and Ti-bases are as follows.
<table>
<tr><th rowspan="2">Implant system (Manufacturer)</th><th rowspan="2">Platform</th><th rowspan="2">Diameter</th><th colspan="2">Sirona Ti-base</th></tr>
<tr><th>Name</th><th>Size</th></tr>
<tr><td rowspan="4">Replace, Replace Select (Nobel Biocare)</td><td>NP</td><td>3.5</td><td>TiBase NB RS 3.5 L</td><td rowspan="4">L</td></tr>
<tr><td>RP</td><td>4.3</td><td>TiBase NB RS 4.3 L</td></tr>
<tr><td>WP</td><td>5.0</td><td>TiBase NB RS 5.0 L</td></tr>
<tr><td>6.0</td><td>6.0</td><td>TiBase NB RS 6.0 L</td></tr>
<tr><td rowspan="2">Nobel Active, NobelReplace Conical Connection (Nobel Biocare)</td><td>NP</td><td>3.5</td><td>TiBase NB A 4.5 L</td><td rowspan="2">L</td></tr>
<tr><td>RP</td><td>4.3/5.0</td><td>TiBase NB A 5.0 L</td></tr>
<tr><td rowspan="2">Bone Level (Straumann)</td><td>NC</td><td>3.3</td><td>TiBase S BL 3.3 L</td><td rowspan="2">L</td></tr>
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<tr><td rowspan="6">Nobel Biocare</td><td rowspan="3">Replace</td><td>NP</td><td>3.5</td></tr>
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<tr><td rowspan="2">Active</td><td>6.0</td><td>6.0</td></tr>
<tr><td>NP</td><td>3.5</td></tr>
<tr><td>RP</td><td>4.3/5.0</td></tr>
<tr><td rowspan="2">Branemark</td><td>NP</td><td>3.3</td></tr>
<tr><td>RP</td><td>3.75/4.0</td></tr>
<tr><td rowspan="3">Straumann</td><td rowspan="3">Synocta</td><td>NN (3.5mm)</td><td>3.3</td></tr>
<tr><td>RN (4.8mm)</td><td>3.3/4.1/4.8</td></tr>
<tr><td>WN (6.5mm)</td><td>4.8</td></tr>
<tr><td rowspan="2">Bone Level</td><td>NC (3.3mm)</td><td>3.3</td></tr>
<tr><td>RC (4.1mm/4.8mm</td><td>4.1/4.8</td></tr>
<tr><td rowspan="4">Dentsply Sirona Implants</td><td rowspan="2">Osseospeed</td><td>3.5/4.0</td><td>3.5 S / 4.0 S</td></tr>
<tr><td>4.5/5.0</td><td>4.5/5.0/5.0 S</td></tr>
<tr><td rowspan="2">Xive</td><td>3.4</td><td>3.4</td></tr>
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<tr><td>NP</td><td>3.5</td></tr>
<tr><td>RP</td><td>4.3/5.0</td></tr>
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<tr><td>RP</td><td>3.75/4.0</td></tr>
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<tr><td rowspan="4">Dentsply Sirona Implants</td><td rowspan="2">Osseospeed</td><td>3.5/4.0</td><td>3.5 S / 4.0 S</td></tr>
<tr><td>4.5/5.0</td><td>4.5/5.0/5.0 S</td></tr>
<tr><td rowspan="2">Xive</td><td>3.4</td><td>3.4</td></tr>
<tr><td>3.8</td><td>3.8</td></tr>
<tr><td></td><td></td><td>4.5</td><td>4.5</td></tr>
<tr><td></td><td></td><td>5.5</td><td>5.5</td></tr>
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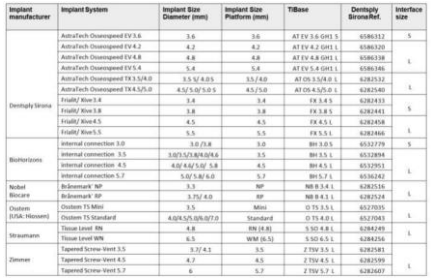
</td>
<td>The compatible Implant systems, titanium bases and CAD/CAM systems are shown below:
-Implant Systems:
- Dentsply Sirona: AstraTech OsseoSpeed, Frialit/Xive (K130999, K013867)
- BioHorizons Implant System: Internal Connection (K143022, K071638, K093321, K042429),
- Osstem: TS Implant System (K121585)
- Straumann: Tissue Level RN/WN (K061176)
- Nobel Biocare: Branemark (K022562)
- Zimmer: Tapered Screw-Vent (K061410)
- Camlog: Camlog Screw-Line, Conelog Screw-Line, iSy (K083496, K113779, K133991)
- CAD/CAM Systems: Sirona Dental CAD/CAM System (K181520)
- Titanium Bases

Dentsply Sirona TiBase

<table>
<tr><th>Implant manufacturer</th><th>Implant System</th><th>Implant Size Diameter (mm)</th><th>Implant Size Platform (mm)</th><th>TiBase</th><th>Dentsply SironaRef.</th><th>Interface size</th></tr>
<tr><td rowspan="9">Dentsply Sirona</td><td>AstraTech Osseospeed EV 3.6</td><td>3.6</td><td>3.6</td><td>AT EV 3.6 GH1 S</td><td>6586312</td><td>S</td></tr>
<tr><td>AstraTech Osseospeed EV 4.2</td><td>4.2</td><td>4.2</td><td>AT EV 4.2 GH1 L</td><td>6586320</td><td rowspan="2">L</td></tr>
<tr><td>AstraTech Osseospeed EV 4.8</td><td>4.8</td><td>4.8</td><td>AT EV 4.8 GH1 L</td><td>6586338</td></tr>
<tr><td>AstraTech Osseospeed EV 5.4</td><td>5.4</td><td>5.4</td><td>AT EV 5.4 GH1 L</td><td>6586346</td><td rowspan="2">L</td></tr>
<tr><td>AstraTech Osseospeed TX 3.5/4.0</td><td>3.5 S/ 4.0 S</td><td>3.5/4.0</td><td>AT OS 3.5/4.0 L</td><td>6282532</td></tr>
<tr><td>AstraTech Osseospeed TX 4.5/5.0</td><td>4.5/ 5.0/ 5.0 S</td><td>4.5/5.0</td><td>AT OS 4.5/5.0 L</td><td>6282540</td><td>L</td></tr>
<tr><td>Frialit/ Xive 3.4</td><td>3.4</td><td>3.4</td><td>FX 3.4 S</td><td>6282433</td><td rowspan="2">S</td></tr>
<tr><td>Frialit/ Xive 3.8</td><td>3.8</td><td>3.8</td><td>FX 3.8 S</td><td>6282441</td></tr>
<tr><td>Frialit/ Xive 4.5</td><td>4.5</td><td>4.5</td><td>FX 4.5 L</td><td>6282458</td><td rowspan="2">L</td></tr>
<tr><td>Frialit/ Xive 5.5</td><td>5.5</td><td>5.5</td><td>FX 5.5 L</td><td>6282466</td></tr>
<tr><td rowspan="4">BioHorizons</td><td>Internal connection 3.0</td><td>3.0 /3.8</td><td>3.0</td><td>BH 3.0 S</td><td>6532779</td><td>S</td></tr>
<tr><td>Internal connection 3.5</td><td>3.0/3.5/3.8/4.0/4.6</td><td>3.5</td><td>BH 3.5 L</td><td>6532894</td><td rowspan="3">L</td></tr>
<tr><td>Internal connection 4.5</td><td>4.0/ 4.6/ 5.0/ 5.8</td><td>4.5</td><td>BH 4.5 L</td><td>6532951</td></tr>
<tr><td>Internal connection 5.7</td><td>5.0/ 5.8/ 6.0</td><td>5.7</td><td>BH 5.7 L</td><td>6536242</td></tr>
<tr><td>Nobel Biocare</td><td>Brånemark® NP</td><td>3.3</td><td>NP</td><td>NB B 3.4 L</td><td>6282516</td><td>L</td></tr>
<tr><td>Osstem (USA: Hiossen)</td><td>Brånemark® RP</td><td>3.75/ 4.0</td><td>RP</td><td>NB B 4.1 L</td><td>6282524</td><td>L</td></tr>
<tr><td rowspan="2">Straumann</td><td>Osstem TS Mini</td><td>3.5</td><td>Mini</td><td>O TS 3.5 L</td><td>6527035</td><td>L</td></tr>
<tr><td>Osstem TS Standard</td><td>4.0/4.5/5.0/6.0/7.0</td><td>Standard</td><td>O TS 4.0 L</td><td>6527043</td><td>L</td></tr>
<tr><td rowspan="3">Zimmer</td><td>Tissue Level RN</td><td>4.8</td><td>RN (4.8)</td><td>S SO 4.8 L</td><td>6284249</td><td>L</td></tr>
<tr><td>Tissue Level WN</td><td>6.5</td><td>WM (6.5)</td><td>S SO 6.5 L</td><td>6284256</td><td rowspan="3">L</td></tr>
<tr><td>Tapered Screw-Vent 3.5</td><td>3.7/ 4.1</td><td>3.5</td><td>Z TSV 3.5 L</td><td>6282581</td></tr>
<tr><td>Tapered Screw-Vent 4.5</td><td>4.7</td><td>4.5</td><td>Z TSV 4.5 L</td><td>6282599</td><td rowspan="2">L</td></tr>
<tr><td>Tapered Screw-Vent 5.7</td><td>6</td><td>5.7</td><td>Z TSV 5.7 L</td><td>6282607</td></tr>
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Subject device: KATANA Zirconia ONE For IMPLANT	Primary predicate device: Sirona Dental CAD/CAM System with CEREC Chairside software (K193408)	Reference device: Sirona Dental CAD/CAM System (K181520)	Reference device: IPS e.max CAD Abutment Solutions- extra systems (K191382)

	4.5	4.7	TiBase Z TSV 4.5 L	
	5.7	6	TiBase Z TSV 5.7 L	

Manufacturer	Name of Implant System	Implant Size	
		Platform	Diameter
Dentsply Sirona Implants	Osseospeed EV	3.6	3.6
		4.2	4.2
		4.8	4.8
		5.4	5.4
	Ankylos	C/X	A, B, C, D
	Osseospeed TX	3.0	3.0
		3.5/4.0	3.5/4.0
		4.5/5.0	4.5/5.0
Biomet 3i	Osseotite	3.4	3.25
		4.1	3.75
			4.1
			3/4
		5.0	5.0
			4/5
	Certain	3.4	3.25
			4/3
			3/4/3
		4.1	4.0
			4/5/4
			5/4
		5.0	5.0
			4/5
Zimmer	Tapered Screw-Vent	3.5	3.7/4.1
		4.5	4.7
		5.7	6
Thommen Medical	Thommen Medical Implants	3.5	3.5
		4	4
		4.5	4.5
		5	5
		6	6
Osstem / Hiossen	Osstem TS Implant System	Mini	3.5
	Hiossen Implant System	Regular	4.0/4.5/5.0/6.0/7.0

Manufacturer	Name of Implant System	Implant Size	
		Platform	Diameter
BioHorizons (Internal Connection)	Tapered 3.0,Tapered plus	3.0	3.0/3.4/3.8
	Tapered internal		3.0
	Tapered plus	3.5	4.6
	Tapered internal, Tapered internal tissue level		3.0/3.8
	Internal dental implant		3.5
	Single stage dental implants		3.5/4.0
	Tapered Plus	4.5	5.8
	Tapered internal, Tapered internal tissue level		4.6
	Internal dental implant		4.0
	Single stage dental implants		4.0/5.0
	Tapered internal, Tapered internal tissue level	5.7	5.8
	Internal dental implant, Single stage dental implants		5.0/6.0

Manufacturer	Name of Implant System	Implant Size	
		Platform	Diameter
Dentsply Sirona Implants	Osseospeed EV	3.6	3.6
		4.2	4.2
		4.8	4.8
		5.4	5.4
	Ankylos	C/X	A, B, C, D
Biomet 3i	Osseotite	3.4	3.25
		4.1	3.75
			4.1
			3/4
		5.0	5.0
			4/5
	Certain	3.4	3.25
			4/3
			3/4/3
		4.1	4.0
			4/5/4
			5/4
		5.0	5.0
			4/5
Zimmer	Tapered Screw-Vent	3.5	3.7/4.1
		4.5	4.7
		5.7	6
Thommen Medical	SPI ELEMENT, SPI ELEMENT INICELL, SPI CONTACT INICELL	3.5	3.5
		4	4
		4.5	4.5
		5	5
		6	6
Osstem / Hiossen	Osstem TS Implant System	Mini	3.5
	Hiossen Implant System	Regular	4.0/4.5/5.0/6.0/7.0

Manufacturer	Name of Implant System	Implant Size	
		Platform	Diameter
BioHorizons (Internal Connection)	Tapered 3.0,Tapered plus	3.0	3.0/3.4/3.8
	Tapered internal		3.0
	Tapered plus	3.5	4.6
	Tapered internal, Tapered internal tissue level		3.0/3.8
	Internal dental implant		3.5
	Single stage dental implants		3.5/4.0
	Tapered Plus	4.5	5.8
	Tapered internal, Tapered internal tissue level		4.6
	Internal dental implant		4.0
	Single stage dental implants		4.0/5.0
	Tapered internal, Tapered internal tissue level	5.7	5.8
	Internal dental implant, Single stage dental implants		5.0/6.0

Camlog TiBase

Implant manufacturer	Implant System	Implant Size Diameter (mm)	Implant Size Platform (mm)	TiBase	Camlog Ref.	Interface size
Camlog	Camlog Screw-Line 3.3	3.3	3.3	CAMLOG® Titanium base CAD/CAM, for Ø 3.3 mm	K2244.3348	S
	Camlog Screw-Line 3.8	3.8	3.8	CAMLOG® Titanium base CAD/CAM, for Ø 3.8 mm	K2244.3848	
	Camlog Screw-Line 4.3	4.3	4.3	CAMLOG® Titanium base CAD/CAM, for Ø 4.3 mm	K2244.4348	
	Camlog Screw-Line 5.0	5.0	5.0	CAMLOG® Titanium base CAD/CAM, for Ø 5.0 mm	K2244.5048	L
	Camlog Screw-Line 6.0	6.0	6.0	CAMLOG® Titanium base CAD/CAM, for Ø 6.0 mm	K2244.6048	
	Conelog Screw-Line 3.3	3.3	3.3	CONELOG® Titanium base CAD/CAM, for Ø 3.3 mm, GH 0.8 mm	C2242.3308	S
				CONELOG® Titanium base CAD/CAM, for Ø 3.3 mm, GH 2.0 mm	C2242.3320	
	Conelog Screw-Line 3.8	3.8	3.8	CONELOG® Titanium base CAD/CAM, for Ø 3.8 mm, GH 0.8 mm	C2242.3808	
				CONELOG® Titanium base CAD/CAM, for Ø 3.8 mm, GH 2.0 mm	C2242.3820	
	Conelog Screw-Line 4.3	4.3	4.3	CONELOG® Titanium base CAD/CAM, for Ø 4.3 mm, GH 0.8 mm	C2242.4308	
				CONELOG® Titanium base CAD/CAM, for Ø 4.3 mm, GH 2.0 mm	C2242.4320	
	Conelog Screw-Line 5.0	5.0	5.0	CONELOG® Titanium base CAD/CAM, for Ø 5.0 mm, GH 0.8 mm	C2242.5008	L
				CONELOG® Titanium base CAD/CAM, for Ø 5.0 mm, GH 2.0 mm	C2242.5020	
	Ily 3.8 / 4.4 / 5.0	3.8/ 4.0/ 5.0	3.8/ 4.4/ 5.0	Ily® Titanium base CAD/CAM, Ø 4.5 mm, GH 0.8 mm	P2244.4408	S
				Ily® Titanium base CAD/CAM, Ø 4.5 mm, GH 2.0 mm	P2244.4420	
				Ily® Titanium base CAD/CAM, Ø 5.2 mm, GH 0.8 mm	P2244.5008	L
				Ily® Titanium base CAD/CAM, Ø 5.2 mm, GH 2.0 mm	P2244.5020	

5-2. Design

In the design such as the combination, indications for use, KATANA Zirconia ONE For IMPLANT is substantially equivalent to the primary predicate device and the reference device.

Design

Subject device: **KATANA Zirconia ONE For IMPLANT**	**Primary predicate device:** **Sirona Dental CAD/CAM System with CEREC Chairside software (K193408)**
CAD/CAM Software Version	
CEREC SW, InLab Software	CEREC SW
Titanium Base Components	
Sirona TiBase Diameter: 3.3 mm - 6.0 mm	Sirona TiBase Diameter: 3.0 mm - 7.0 mm
Abutment Angulation 0° ~ 20°	Maximal Abutment Angulation 20°
Material (TiBase and Screw) Titanium alloy	Material (TiBase and Screw) Titanium alloy
Mesostructure material	
KATANA Zirconia ONE (For IMPLANT)	inCoris ZI
Block Material: Zirconium oxide ceramic ISO 6872:2015	Block Material: Zirconium oxide ceramic
Abutment post height*1 min.4.0 mm ~ max.16.7 mm Angulation 0° ~ 20° Wall thickness min.0.8 mm ~ max.9.5 mm Diameter min.3.3 mm ~ max.6.0 mm Gingival height 1.0 mm	Block Dimensions: 24 mm (L) × 23 mm (W) × 21.5 mm (H)
Available Shades: A1, A2, A3, A3.5, B1, B2, C1, C2, D2, NW (10 shades)	Available Shades: F0.5, F2

*1 The abutment post height is considered by FDA to be the “stump” portion above the gingival collar, to which the restorations attach.

5-3. Material Composition of mesostructured material

The mesostructured material of KATANA Zirconia ONE For IMPLANT has the identical chemical composition as the reference device, KATANA Zirconia Block (K190436).

5-4. Technological Characteristics

The mesostructured material of KATANA Zirconia ONE For IMPLANT is offered in a block form, with a mandrel attachment, to permit securing it into a CAD/CAM machine for milling into its final form.

The mesostructured material of KATANA Zirconia ONE For IMPLANT and its predicate device (inCoris Zl, IPS e.max CAD Abutment Solutions) do not share same chemical or physical properties. However it was considered that there were no differences among the mesostructure material of KATANA Zirconia ONE For IMPLANT, the predicate device as the following reasons.

- The mesostructure material of KATANA Zirconia ONE For IMPLANT is similar with minor differences in the compatible implant systems. The intended use for each is similar. Mesostructure material of KATANA Zirconia ONE For IMPLANT, the inCoris ZI, and IPS e.max CAD have similar functions as the ceramic for the mesostructure to complete the two-piece abutment. Moreover, all three are mesostructures intended to serve as milled components of dental implant abutments and abutment crowns, and all three share implant compatibilities with the same Sirona TiBase devices.

On the other hand, the mesostructure material of KATANA Zirconia ONE For IMPLANT has have an access hole compatible with intended TiBase (K193408, K200191) to allow the mesostrcture or abutment crown bonded to a titanium base to be connected to the implant. The mesostructure material of KATANA Zirconia ONE For IMPLANT has identical chemical properties as the reference device, KATANA Zirconia Block (K190436) in geometry, with the exception of an access hole.

It was considered that there were no differences concerning chemical compositions and physical properties between the mesostructure material of KATANA Zirconia ONE For IMPLANT and the reference device (KATANA Zirconia Block) as the following reasons.

- The mesostructure material of KATANA Zirconia ONE For IMPLANT has the identical chemical composition, equivalent biocompatibility and meet physical properties such as ISO 6872:2015.

Concerning the primary predicate device, Sirona Dental CAD/CAM System with CEREC Chairside software (K193408), the indication for use of the subject device is equivalent.
The subject device is a new mesostructured material to be added to this system and is equivalent in technical characteristics to the mesostructure material of the predicate device. In addition, Titanium Base (TiBase) and CAD/CAM systems that have been certified under this system is used for the subject device.
For these reasons, it was selected as the predicate device because it was judged to be the most similar to the subject device. The mesostructure material of the subject device was compared with InCoris, which is as the mesostructure included Sirona Dental CAD/CAM System.

For this abutment system, the titanium Ti-Base already received 510(k) clearance (K193408, K200191, K181520) by Dentsply Sirona for use with the Sirona CAD/CAM System for each of the identified compatible implant bodies.

7. Non-Clinical Performance Testing

7-1. Compatibility to standards

KATANA Zirconia ONE For IMPLANT:

- ISO 6872: 2015 – Dentistry – Ceramic materials
- ISO 14801: 2016 − Dentistry – Implants – Dynamic fatigue test for endosseous dental implants

Fatigue testing was performed for the worst- case representative devices according to ISO 14801.

7-2. Sterilization

The sterilization instructions are validated per ISO 17665-1. Sterilization validation achieved an SAL of at least 10^{-6}.

7-3. Biocompatibility

We evaluated the biocompatibility of the subject device referring to “Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" Guidance for Industry and Food and Drug Administration Staff”, ISO 10993 series and ISO 7405.

7-4. MR Environment Condition

Non-clinical worst-case MRI review was performed to evaluate the subject device in the MRI environment using scientific rationale and published literature (e.g., Terry O et al. Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices. Journal of Testing and Evaluation. doi: 10.1520, JTE20190096, Vol. 49, No. 2, 2021), based on the entire system including all variations (all compatible implant bodies, titanium dental abutments, and fixation screws: refer to the table “Compatible implant systems and TiBase” in Indication for use) and material composition.

Rationale addressed parameters per the FDA guidance “Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment,” including magnetically induced displacement force and torque.

7-5. Compatibility with the CAD/CAM system of Dentsply Sirona

Dentsply Sirona distributes CAD/CAM systems which shall include the currently marketed devices and any enhancements, improvements, or successors thereto (collectively the "Devices") being used to mill inlays, onlays, crowns, crown and bridge frameworks, and similar dental restorations from pre-manufactured blocks of various composition (known and referenced as "Blanks").

There is the business agreement between Kuraray Noritake Dental, which manufactures the pre-manufactured blocks, and Dentsply Sirona, which distributes the devices. This Agreement provides for the licensing from Dentsply Sirona to Kuraray Noritake Dental of the Brands and the provision of the know-how required for the manufacturing of KURARAY branded block-formed Blanks using the Devices and their control software.

And under the above business agreement, Dentsply Sirona disclosed to Kuraray Noritake its requirements for the mesostructure, such as shape and size. Kuraray Noritake Dental has developed a manufacturing process that stably reproduced this mesostructure to meet Dentsply Sirona's requirements.

This is the cooperative relationship between Kuraray Noritake Dental and Dentsply Sirona to demonstrate the compatibility of the mesostructure and TiBase based on the business agreement.

8. Clinical Performance Data

Not applicable. No human clinical testing was performed to support the substantial equivalence of the subject device.

9. Conclusion

This submission information including the nonclinical testing provided supports that the subject device is substantially equivalent to the predicate devices.