Newton Implant Systems, Inc
% Joyce Kwon
CEO
Provision Consulting Group, Inc.
13925 City Center Street, Suite 200
Chino Hills, California 91709

April 11, 2024

Re: K221847
Trade/Device Name: Ni2 Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: March 11, 2024
Received: March 12, 2024

Dear Joyce Kwon:

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)*
K221847

Device Name
Ni2 Impant System

Indications for Use *(Describe)*

The Ni2 Implant System is indicated for surgical placement in the upper and lower jaw arches, to provide a root form means for single or multiple units' prosthetic attachment to restore a patient's chewing function. The smaller Ni2 dental implants (Ø3.6, 4.0, 5.0 mm) can be placed with a conventional two stage surgical process with an option for transmucosal healing or they can be placed in a single stage surgical process for immediate loading when good primary stability is achieved with appropriate occlusal loading. The larger Ni2 Implants (Ø6.0, 7.0 mm) can be placed with a conventional two stage surgical process with an option for transmucosal healing and are indicated for the molar region with delayed loading.

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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510(k) Summary

510(k) Submitter
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joyce@provisionfda.com

Date Prepared
4/10/2024

Device Information
- Trade Name: Ni2 Implant System
- Common Name: Endosseous Dental Implant
- Classification Name: Implant, Dental, Endosseous, Root-Form
- Regulation Number: 21 CFR 872.3640
- Device Class: Class II
- Product Code: DZE

Predicate Devices
Fixture:
- S-Plant Dental Implant System (K221866)

Reference Device
- DIO UF HSA Internal Sub-merged Implant System (K122519)
- Noris Medical Dental Implant System -Cortical (K210852)

Indication for Use

The Ni2 Implant System is indicated for surgical placement in the upper and lower jaw arches, to provide a root form means for single or multiple units' prosthetic attachment to restore a patient's chewing function. The smaller Ni2 dental implants (Ø3.6, 4.0, 5.0 mm) can be placed with a conventional two stage surgical process with an option for transmucosal healing or they can be placed in a single stage surgical process for immediate loading when good primary stability is achieved with

appropriate occlusal loading. The larger Ni2 Implants (Ø6.0, 7.0 mm) can be placed with a conventional two stage surgical process with an option for transmucosal healing and are indicated for the molar region with delayed loading.

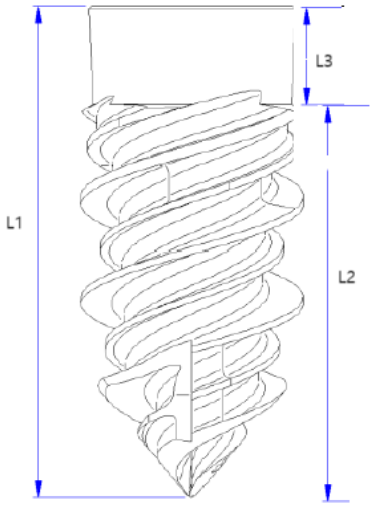
Device Description

The Ni2 Implant System is comprised of dental implants, superstructures, instruments for prosthetics and surgical instruments. The Ni2 Implant System is specially designed for use in dental implant surgery. A successfully osseointegrated implant will achieve a firm implant when surgically implanted under controlled conditions. They are intended for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple unit restorations.
The Ni2 Implant System, fixtures are made of commercial pure titanium, grade 4 (ASTM F67) which have a S.L.A (Sand blasted large grit acid etched) treated surface and supplied sterile (gamma radiation). These fixtures can be used one stage surgery method or two stage surgery method. And that are surgically inserted into the upper and/or lower jawbone. The fixtures replace tooth root as providing a stable foundation for restorations.

Geometrically, the implant is screw type. An abutment is connected to the implant through a tapered joint. The Ni2 fixtures are compatible with the abutments which have been previously cleared in K221866.

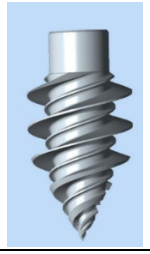
The non-threaded section of the implant body is also SLA surface treated.

Substantial Equivalent Comparison Chart



L1: Endosseous Implant Length
L2: Threaded SLA treated length
L3: Non-threaded SLA treated length

	Subject	Primary Predicate	Reference device	Reference device
Device Name	Ni2 Implant System	S-Plant Dental Implant System	DIO UF HSA Internal Sub-merged Implant System	Noris Medical Dental lmplants System -Cortical
Regulation #	21 CFR 872.3640	21 CFR 872.3640	21 CFR 872.3640	21 CFR 872.3640
Regulation Name	Endosseous Dental Implant	Endosseous Dental Implant	Endosseous Dental Implant	Endosseous Dental Implant
Classification	Class 2	Class 2	Class 2	Class 2
510(k) #	K221847	K221866	K122519	K210852
Product Code	DZE	DZE	DZE	DZE
Manufacturer	IDIS Co., Ltd.	IDIS Co., Ltd.	DIO Corporation	Noris Medical Ltd
Intended Use	Functional and esthetic rehabilitation of the edentulous mandible or maxilla	Functional and esthetic rehabilitation of the edentulous mandible or maxilla	Functional and esthetic rehabilitation of the edentulous mandible or maxilla	Functional and esthetic rehabilitation of the edentulous mandible or maxilla
Indications for Use	The Ni2 Implant System is indicated for surgical placement in the upper and lower jaw arches, to provide a root form means for single or multiple units' prosthetic attachment to restore a patient's chewing function. The smaller Ni2 dental implants (Ø3.6, 4.0, 5.0 mm) can be placed with a conventional two stage surgical process with an option for transmucosal healing or they can be placed in a single stage surgical process for immediate loading when good primary stability is achieved with appropriate occlusal loading. The larger Ni2 Implants (Ø6.0, 7.0 mm) can be placed with a conventional two stage surgical process with an option for transmucosal healing and are indicated for the molar region with delayed loading.	The S-Plant Dental Implant System is indicated for surgical placement in the upper and lower jaw arches, to provide a root form means for single or multiple units' prosthetic attachment to restore a patient's chewing function. The smaller S-Plant Dental Implants (Ø3.4, 3.6, 3.8, 4.2, 4.7, 5.2 mm) can be placed with a conventional two stage surgical process with an option for transmucosal healing or they can be placed in a single stage surgical process for immediate loading when good primary stability is achieved with appropriate occlusal loading. The larger S-Plant Dental Implants (Ø6.0, 7.0 mm) can be placed with a conventional two stage surgical process with an option for transmucosal healing and are indicated for the molar region with delayed loading.	The DIO UF I-ISA Internal Sub-Merged Implant System is indicated for surgical placement in the upper and lower Jaw arches, to provide a root form means for single or multiple units' prosthetic attachment to restore a patient's chewing Function. The smaller (Ø3.8 ~ Ø5.5) implants can be placed with a conventional two stage surgical process with an option for transmucosal healing or they can be placed in a single stage surgical process for immediate loading when good primary stability is achieved with appropriate occlusal loading. The larger (Ø6.0 ~ Ø7.0) implants can be placed with a conventional two stage surgical process with an option for transmucosal healing and are indicated for the molar region with delayed loading.	Noris Medical Dental Implants System is intended to replace missing tooth/teeth in either jaw for supporting prosthetic devices that may aid in restoring the patient's chewing function. The procedure can be accomplished in a one--stage or two-stage surgical operation. All implants are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

		Dual abutments are intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures. Healing abutments are used to make a natural soft tissue shape before setting up prosthetics and removing cover screw after osseointegration. Cover Screws are used to protect the internal portion of the implant, preventing soft tissue growth into the implant, facilitating provisional restorations when necessary, and enabling the transition to final restoration components once osseointegration is complete.		
Prosthetic Interface Connection	Tapered conical hex	Tapered conical hex	Tapered conical hex	Internal Hex
				

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<td>Fixture Diameter and Endosseous Length (mm)</td>
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<tr><th>Diameter (mm)</th><th>L1 (mm)</th></tr>
<tr><td>Ø3.6</td><td>8.5, 10.0, 11.5, 13.0, 15.0</td></tr>
<tr><td>Ø4.0</td><td>7.0, 8.5, 10.0, 11.5, 13.0, 15.0</td></tr>
<tr><td>Ø5.0</td><td>7.0, 8.5, 10.0, 11.5, 13.0, 15.0</td></tr>
<tr><td>Ø6.0</td><td>7.0, 8.5, 10.0, 11.5</td></tr>
<tr><td>Ø7.0</td><td>7.0, 8.5</td></tr>
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<table>
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<tr><td>Ø3.6</td><td>8.5, 10.0, 11.5, 13.0, 15.0</td></tr>
<tr><td>Ø3.8</td><td>7.0, 8.5, 10.0, 11.5, 13.0, 15.0</td></tr>
<tr><td>Ø4.2</td><td>7.0, 8.5, 10.0, 11.5, 13.0</td></tr>
<tr><td>Ø4.7</td><td>7.0, 8.5, 10.0, 11.5, 13.0</td></tr>
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</td>
<td>
<table>
<tr><th>Diameter (mm)</th><th>Endosseous Length (mm)</th></tr>
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<tr><td>Ø4.5</td><td>7.0, 8.5, 10, 11.5, 13.0, 15.0, 16.0</td></tr>
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<tr><td>Ø5.5</td><td>7.0, 8.5, 10, 11.5, 13.0, 15.0, 16.0</td></tr>
<tr><td>Ø6.0</td><td>7.0, 8.5</td></tr>
<tr><td>Ø7.0</td><td>7.0, 8.5</td></tr>
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<table>
<tr><th>Diameter (mm)</th><th>Endosseous Length (mm)</th></tr>
<tr><td>Ø4.0</td><td>7.5, 9, 12, 14, 16</td></tr>
<tr><td>Ø5.0</td><td>7.5, 9, 12</td></tr>
<tr><td>Ø6.0</td><td>7.5, 9, 12</td></tr>
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<td>Non-Threaded Length (mm)</td>
<td>2.0 mm for all lengths. Length within the bone(and surface treated for osseointegration).</td>
<td>N/A</td>
<td>N/A</td>
<td>For L7.5: 0.7
For L9: 1.0
For L12: 2.0
For L14: 3.0
For L16: 3.5
Length within the bone(and surface treated for osseointegration)</td>
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<td>Fixture Diameter and Threaded Length (mm)</td>
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<tr><td>Ø5.0</td><td>6.8, 8.0, 10.0</td></tr>
<tr><td>Ø6.0</td><td>6.8, 8.0, 10.0</td></tr>
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	Ø7.0: 5.0, 6.5	Ø4.2: 7.0, 8.5, 10.0, 11.5, 13.0 Ø4.7: 7.0, 8.5, 10.0, 11.5, 13.0 Ø5.2: 7.0, 8.5, 10.0, 11.5 Ø6.0: 7.0, 8.5, 10.0, 11.5 Ø7.0: 7.0, 8.5	Ø4.5: 7.0, 8.5, 10, 11.5, 13.0, 15.0, 16.0 Ø5.0: 7.0, 8.5, 10, 11.5, 13.0, 15.0, 16.0 Ø5.5: 7.0, 8.5, 10, 11.5, 13.0, 15.0, 16.0 Ø6.0: 7.0, 8.5 Ø7.0: 7.0, 8.5	
Implant Material	CP Ti Grade 4 (ASTM F67)	CP Ti Grade 4 (ASTM F67)	CP Ti Grade 4 (ASTM F67)	CP Ti Grade 4 (ASTM F67)
Implant Endosseous Surface	S.L.A.	S.L.A.	S.L.A.	RBM (Resorbable Blasting Media)
Implant Placement	Bone Level	Bone Level	Bone Level	Bone Level
Sterilization	Gamma Sterilization	Gamma Sterilization	Gamma Sterilization	Gamma Sterilization
Shelf Life	8 years	8 years	5 years	5 years

Substantial Equivalence Discussion

1. General Indications: Both the subject device and the predicate device share similar overarching indications for use. They are both designed for surgical placement in the upper and lower jaw arches, with the primary goal of providing a root form means for prosthetic attachment to restore a patient's chewing function.
2. Implant Sizes and Surgical Procedures: Both systems offer a range of implant sizes to accommodate various clinical scenarios. The smaller implants of both systems (Ø3.6~ Ø5.2 mm) can be placed using a conventional two stage surgical process, with the option for transmucosal healing. Additionally, both systems provide the flexibility of a single-stage surgical process for immediate loading when there is good primary stability, with appropriate occlusal loading. The non-threaded section of the implant body is also SLA surface treated.
3. Molar Region and Delayed Loading: The larger implants in both systems (Ø6.0 ~ Ø7.0 mm) are specifically indicated for the molar region and involve a conventional two-stage surgical process with an option for transmucosal healing, accompanied by delayed loading. This demonstrates a parallel approach to addressing the unique requirements of the molar region.

Discussion: The comparisons highlight the substantial equivalence between the subject and the predicate device. The similarities in their indications for use, design, implant sizes, and surgical procedures demonstrate that the differences do not impact substantial equivalence.

The minor variations in implant dimensions and specific procedural details are well within the acceptable range for dental implant systems, considering the diverse clinical needs and preferences of practitioners. Both systems provide suitable options for immediate loading and delayed loading based on clinical conditions, indicating flexibility in accommodating various patient cases.

The Ni2 Implant System is similar to the predicate device (K221866) in terms of its design, dimensions, material, surface treatment, intended use, and technological characteristics. The subject device also includes diameters (3.6, 4.0, 5.0mm) that are not covered by the predicate device, but they fall within the range between the diameter of the reference devices (K122519 and K210852) and the diameter of the predicate device. Specifically, K210852 was included as a reference device to support the design of the 2mm of unthreaded SLA surface treated bone level implant body length implanted into the bone as the 2mm of unthreaded SLA surface treated of the subject device falls into the range of the reference device, K210852, which is between 0.7mm ~ 3.5mm.

Non-Clinical Test Data

The non-clinical test data submitted for the Ni2 implant system validates its substantial equivalence to the predicate device. The outcomes collectively support the substantial equivalence of the Ni2 Implant System to the predicate device.

- The subject device will not be labeled as “non-pyrogenic”. Bacterial Endotoxin Testing (LAL) in accordance with USP<85> and USP<161> in K221866.
- Requirements for biological evaluation of the subject device were based on the ISO 10993-1 “Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process. Biocompatibility testing information is leveraged from predicate device, K221866. The Biocompatibility Test was conducted on the K221866 predicate device is leveraged for the subject device because both products are manufactured with similar materials, manufacturer, manufacturing process.
- Referenced from our own predicate K221866, is sterile barrier shelf-life data according to

ASTM F1980 and sterilization validation on Implants according to ISO 11137-1,2,3 referenced in K221866. Validation of the gamma irradiation process was previously conducted for the predicate device, K221866. There has been no change to the manufacturing or sterilization processes.

- SEM (Scanning electron microscopy) images and EDS (Energy Dispersive X-ray Spectroscopy) analysis were conducted on the predicate K221866 and is leveraged from our own prior clearance for the identical SLA surface treatment and manufacturing.

MR Conditional Labeling

Non-clinical worst-case MRI review was performed to evaluate the metallic devices in the MRI environment using scientific rationale and published literature (i.e., Woods, Terry O., Jana G. Delfino, and Sunder Rajan. "Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices." Journal of Testing and Evaluation 49.2 (2019): 783-795), based on the entire system to include all variations (all compatible implant bodies, dental abutments, and fixation screws) and material compositions. The 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.

No clinical studies are submitted.

Conclusions

The Ni2 Implant System is similar to the predicate device (K221866) in terms of its design, dimensions, material, surface treatment, intended use, and technological characteristics. The subject device also includes diameters (3.6, 4.0, 5.0mm) that are not covered by the predicate device, but they fall within the range between the diameter of the reference devices (K122519 and K210852) and the diameter of the predicate device.

The provided non-clinical data have demonstrated substantial equivalence with the predicate device. The non-clinical testing procedures followed the guidelines outlined in the FDA document "Class II Special Controls Guidance Document Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments." The results of the non-clinical testing clearly demonstrate that the Ni2 Implant System is substantially equivalent to the predicate device.