October 12, 2023

Detax GmbH
% Chris Brown
Manager
Aclivi, LLC
3250 Brackley Drive
Ann Arbor, Michigan 48105

Re: K232448
Trade/Device Name: FREEPRINT® splintmaster
Regulatory Class: Unclassified
Product Code: MQC, KMY
Dated: August 11, 2023
Received: August 14, 2023

Dear Chris Brown:

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,

Michael E. Adjodha -S

Michael E. Adjodha, MChE, RAC, CQIA
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)*

K232448

Device Name
FREEPRINT® splintmaster

Indications for Use *(Describe)*

FREEPRINT® splintmaster is a light-curable polymerizable resin intended to be used in conjunction with extra-oral curing light equipment. FREEPRINT® splintmaster is indicated for the fabrication, by additive manufacturing, of orthodontic and dental objects such as mouthguards, nightguards, splints, and repositioners.

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
K232448
DETAX GmbH
FREEPRINT® splintmaster
10/11/2023

ADMINISTRATIVE INFORMATION

Manufacturer Name:	DETAX GmbH Carl-Zeiss-Strasse 4 D-76275 Ettingen, Germany Telephone: +49 7243/510-138	Consultant:	Aclivi, LLC 3250 Brackley Drive Ann Arbor, Michigan 48105 Telephone: +1 810 360-9773
Official Contact:	Markus Stratmann - Divisional Director 3D		Chris Brown - Manager
Email:	Markus.Stratmann@detax.de		acliviconsulting@gmail.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	FREEPRINT® splintmaster
Common Name:	Mouthguard, Prescription
Regulation Name/Number:	Unclassified
Device Class:	Unclassified
Product Code:	MQC, KMY
Review Panel:	Dental
Reviewing Branch:	Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices (OHT1) Dental Devices (DHT1B)

PREDICATE DEVICE INFORMATION

The Subject device in this submission is substantially equivalent in indications, use and design principles to the following Predicate device.

510(k)	Primary Predicate Device Name	Company Name
K211415	GR Splint Resin System	Pro3dure Medical GmbH

510(k)	Secondary Predicate Device Name	Company Name
K183598	KeyPrint KeySplint Soft	Keystone Industries
K203000	KeyPrint KeySplint Hard	Keystone Industries

INDICATIONS FOR USE

FREEPRINT® splintmaster is a light-curable polymerizable resin intended to be used in conjunction with extra-oral curing light equipment. FREEPRINT® splintmaster is indicated for the fabrication, by additive manufacturing, of orthodontic and dental objects such as mouthguards, nightguards, splints, and repositioners.

DEVICE DESCRIPTION

The Subject device is a light-cured methacrylate-based resin used in 3D printers to produce dental mouthguards, nightguards, splints, and repositioners. The Subject device is a viscous solution consisting of methacrylate-based resins, photo initiators and pigment.

The Subject device is used by a dental professional (dentist or dental technician) for the additive Computer-Aided Manufacturing (CAM) of dental mouthguards, nightguards, splints, and repositioners. There are two models of

the Subject device which are referred to as FREEPRINT® splintmaster flex and FREEPRINT® splintmaster taff with slightly different material properties for either a more flexible or rigid final product.

The Subject device resin is used within a validated manufacturing workflow to create the intended dental device. Dental devices fabricated using the Subject device are one-time use, prescription-only devices.

Methacrylates are known materials, commonly used in the dental industry for fixed and removable prosthetic devices due to their physical-chemical, mechanical, and biocompatible properties.

EQUIVALENCE TO MARKETED DEVICE

The Subject device is highly similar to the Predicate devices with respect to Indications for Use and technological principles. The comparison tables below compare the Indications for Use and Technological Characteristics of the Subject and Predicate devices.

Indications For Use

Device	Indications for Use Statement
Subject Device FREEPRINT® splintmaster DETAX GmbH	*FREEPRINT® splintmaster is a light-curable polymerizable resin intended to be used in conjunction with extra-oral curing light equipment. FREEPRINT® splintmaster is indicated for the fabrication, by additive manufacturing, of orthodontic and dental objects such as mouthguards, nightguards, splints, and repositioners.*
Primary Predicate Device GR Splint Resin System (K211415) Pro3dure Medical GmbH	*The GR Splint Resin System is a light-curable polymerizable resin intended to be used in conjunction with extra-oral curing light equipment:* *The GR-10 guide is indicated for the fabrication, by additive manufacturing, of orthodontic and dental objects such as splints.* *The GR-19 OA is indicated for the fabrication, by additive manufacturing, of orthodontic and dental objects such as mouthguards, nightguards, splints, repositioners and retainers.* *The GR-22 flex is indicated for the fabrication, by additive manufacturing, of orthodontic and dental objects such as mouthguards, nightguards, splints, and repositioners.*
Secondary Predicate Device KeyPrint KeySplint Soft (K183598) Keystone Industries	*The KeyPrint® KeySplint Soft™ device is indicated for the fabrication of orthodontic and dental appliances such as mouthguards, nightguards, splints and repositioners.*
Secondary Predicate Device KeyPrint KeySplint Hard (K203000) Keystone Industries	*The KeyPrint" KeySplint Hard™ device is indicated for the fabrication of orthodontic and dental appliances such as mouthguards, nightguards, splints, repositioners and retainers.*

The Subject and Predicate Indications for Use Statements (IFUS) are highly similar differing in the specific device names, specifically with respect to the GR-22 flex model which shares the same intended use as the Subject device. The Secondary Predicate device IFUS are also similar in wording, differing in device names but lacking the specific reference to being used in conjunction with extra-oral curing equipment even though extra-oral curing equipment is used to cure these devices. The slight differences in the wording within Indications for Use Statements does not change the intended use of the Subject and Predicate devices to fabricate orthodontic and dental appliances such as mouthguards, nightguards, splints, and repositioners.

Technological Characteristics

Parameter	Subject Device FREEPRINT® splintmaster DETAX GmbH	Primary Predicate Device GR Splint Resin System (K211415) Pro3dure Medical GmbH	Secondary Predicate Device KeyPrint KeySplint Soft (K183598) Keystone Industries	Secondary Predicate Device KeyPrint KeySplint Hard (K203000) Keystone Industries
Reason for Predicate	n/a	IFUS, Technological Characteristics, Comparative Bench Performance Testing	Comparative Bench Performance Testing	Comparative Bench Performance Testing
Product Code	MQC, KMY	MQC, EBI, KMY	MQC, KMY	MQC, KMY, EBI
Device	Mouthguard, Prescription	Mouthguard, Prescription	Mouthguard, Prescription	Mouthguard, Prescription
Regulatory Class	Unclassified	Unclassified	Unclassified	Unclassified
Intended Use	A light-cured methacrylate-based resin used in conjunction with 3D printers (additive manufacturing) and curing systems to produce mouthguards, nightguards, splints, and repositioners.	A light-cured methacrylate-based resin used in conjunction with additive Computer-Aided Manufacturing (CAM) and curing systems to produce mouthguards, nightguards, splints, and repositioners.	A UV light-cured methacrylate-based resin used for the 3D printing of various dental devices such as mouthguards, nightguards, splints, and repositioners.	A UV light-cured methacrylate-based resin used for the 3D printing of various dental devices such as mouthguards, nightguards, splints, and repositioners.
Technology	3D liquid (light-cured) print resin for dental CAD/CAM	3D liquid (light-cured) print resin for dental CAD/CAM	3D liquid (light-cured) print resin for dental CAD/CAM	3D liquid (light-cured) print resin for dental CAD/CAM
Biocompatible	Yes	Yes	Yes	Yes
OTC or Rx	Rx	Rx	Rx	Rx
Sterile	Non-sterile	Non-sterile	Non-sterile	Non-sterile
Chemical Composition	Methacrylate resin, photo initiator	Methacrylate monomer resin, photo initiator	Methacrylate monomer resin, photo initiator	Methacrylate monomer resin, photo initiator
Polymerization (Curing) Method	UV light, 385 nm w/post curing	UV light, 385-405 nm w/post curing	UV light, 385-405 nm w/post curing	UV light, 385-405 nm w/post curing
Equipment	Validated 3D-Printer and post curing devices	Validated 3D-Printer and post curing devices	Validated 3D-Printer and post curing devices	Validated 3D-Printer and post curing devices
Performance Testing	ISO 20795-2	ISO 20795-2 ASTM D256 ISO 37	ISO 20795-2 ASTM D256 ISO 37	ISO 20795-2 ASTM D256 ISO 37
Biocompatibility Testing	ISO 7405 ISO 10993-1 ISO 10993-3 ISO 10993-5 ISO 10993-10 ISO 10993-11 ISO 10993-17 ISO 10993-18 ISO 10993-23 ISO/TS 21726	ISO 10993 Specific standards not listed in 510(k) Summary document.	ISO 10993 Specific standards not listed in 510(k) Summary document.	ISO 10993 Specific standards not listed in 510(k) Summary document.

Product Code/Device/Classification - The Subject and Predicate devices share highly similar designations. The lack of the secondary EBI Product Code does not impact or change the intended use of the Subject device.

Intended Use - The Subject and Predicate devices are Highly Similar in their intended use, effectively conveying the same intended use with slight differences in wording.

Biocompatible/Rx/Sterility - The Subject and Predicate devices share the same designations.

Chemical Composition - The Subject and Predicate devices are the same in they are both UV-light cured liquid methacrylate-based resins with photo initiator(s). Slight differences in chemical composition do not change the intended use of the Subject and Predicate devices to be used in the fabrication of dental mouthguards, nightguards, splints, and repositioners. The Subject device has demonstrated suitability for intended use through material non-clinical performance testing.

Polymerization (Curing) Method/Equipment - The Subject and Predicate devices are the same in that they are both light-cured polymer resins encompassing the same range of curing wavelengths and used with validated 3D printer/post-curing workflows. Any differences in the curing light wavelength does not change the intended use of the Subject and Predicate devices to be used in the fabrication of the intended dental devices.

Performance Testing – The Subject and Predicate devices were tested by their respective sponsors to the same ISO 20795-2 material property standard, meeting most of the requirements of the standard. Comparative testing was performed with the Subject and Predicate devices to ISO 20795-2, ISO 527-1 and ISO 179-1 which demonstrated similar performance for the ISO 20795-2 properties as well as tensile strength, elongation at break and Charpy Impact.

Biocompatibility - The Subject and Predicate devices are similar in the standards and biological endpoints the devices were evaluated to. Slight differences in the standards and tested endpoints do not change the intended use of the Subject and Predicate devices.

Overall, the Technological Characteristics of the Subject and Predicate devices are the Same or Highly Similar. Technological differences between the Subject and Predicate devices have been evaluated through non-clinical performance testing. The results of the tests performed show that Subject device meets the requirements mentioned in the applicable standards and confirm that the Subject device performs similarly to the Predicate devices.

CLINICAL AND ANIMAL TESTING

The performance of methacrylate-based polymer resins in the clinical environment has been well established. No clinical or animal testing data is included in this submission.

NON-CLINICAL PERFORMANCE TESTING

Validation of the manufacturing process and compatible equipment was performed demonstrating consistency of the process output with that of the process input.

Physical property testing was performed on the Subject device to ISO 20795-2, *Dentistry — Base polymers — Part 2: Orthodontic base polymers*. Performance testing on the Subject device was performed for the surface finish, shape capability, color, freedom from porosity, flexural strength, flexural modulus, maximum stress intensity factor, total work fracture, water sorption, water solubility endpoints identified in ISO 20795-2. Comparative material property testing was also performed with the Predicate devices to these endpoints demonstrating similar performance.

A biological evaluation was performed on the Subject device. Chemical characterization was performed to ISO 10993-18 with a risk assessment performed according to ISO 10993-17 and ISO/TS 21726. Biocompatibility testing was performed on the Subject device according to ISO 10993-1:2018 and ISO 7405:2014 according to the standards listed in the Technological Characteristics comparison table above.

An MRI safety assessment was performed on the Subject device to support MR Safety labeling as required by the FDA guidance "*Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment*".

Non-clinical performance testing of the Subject device met the acceptance criteria for each validation and test described above. This non-clinical performance testing demonstrates that the Subject device is suitable for intended use.

CONCLUSION

Overall, the Indications for Use statements for the Subject and Predicate devices are highly similar differing only in device name and slightly in use duration. Overall, the Technological Characteristics of the Subject device are the same or highly similar to the Predicate device with any differences mitigated through non-clinical performance testing.

Overall, these similarities between the Subject and Predicate devices, support a determination of substantial equivalence.