



November 7, 2019

New Stetic S.A.
% Chris Brown
Manager
Aclivi Consulting
6455 Farley Road
Pinckney, Michigan 48169

Re: K192153
Trade/Device Name: Portux CAD/CAM Disc
Regulation Number: 21 CFR 872.3770
Regulation Name: Temporary Crown And Bridge Resin
Regulatory Class: Class II
Product Code: EBG, EBI, MQC
Dated: July 17, 2019
Received: August 9, 2019

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

for Srinivas Nandkumar, Ph.D.
Acting Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K192153

Device Name

Portux CAD/CAM Disc

Indications for Use (Describe)

For the fabrication of crowns, bridges and structures for implant supported provisional removable denture and appliance prosthetics.

- Provisional anterior and posterior crowns & bridges
- Implant and abutment supported prosthetics.
- Partial, complete and hybrid denture prosthetics (base and teeth) – Removable appliances (splint)

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
New Stetic S.A.
Portux CAD/CAM Disc
K192153
11/5/2019

5.1 ADMINISTRATIVE INFORMATION

Manufacturer Name New Stetic S.A.
Carrera 53 No. 50 - 09
Guarne – Antioquia
Colombia
Telephone: +57 4 550 00 00
Fax: +57 4 551 31 34

Official Contact Juan David Jaramillo G. - General Manager
Email: infocolombia@newstetic.com

5.2 DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name: Portux CAD/CAM Disc
Common Name: Crown And Bridge, Temporary Resin

Regulation Name: Temporary Crown And Bridge Resin
Regulation Number: 21 CFR 872.3770
Device Class: Class II
Product Code: EBG, EBI, MQC

Classification Panel: Dental Products Panel
Reviewing Branch: Dental Devices Branch

5.3 PREDICATE DEVICE INFORMATION

The devices within this submission are substantially equivalent in indications, intended use and design principles to the following Primary Predicate device:

510(k)	Primary Predicate Device Name	Company Name
K180578	Harvest Dental Polymer Blocks	Harvest Dental Products, LLC

5.4 DEVICE DESCRIPTION

The Subject device are discs made of poly methyl methacrylate (PMMA), a known material used in the dental field due their physical-chemical, mechanical and biocompatibility properties. These discs are intended use with dental CAD/CAM equipment to produce a variety of provisional prosthetic restorations or devices. The discs are available in a variety of disc configurations to accommodate different commercial dental CAD/CAM machines fixture requirements. In addition, the CAD/CAM discs are available in a wide variety of heights and colors to facilitate matching of patient tooth or tissue shades.

5.5 INDICATIONS FOR USE

For the fabrication of crowns, bridges and structures for implant supported provisional removable denture and appliance prosthetics.

- Provisional anterior and posterior crowns & bridges
- Implant and abutment supported prosthetics.
- Partial, complete and hybrid denture prosthetics (base and teeth) – Removable appliances (splint)

5.6 EQUIVALENCE TO MARKETING DEVICE

The comparison table below compares the Indications for Use and technological characteristics of the Subject and Primary Predicate devices.

Substantial Equivalence Comparison Table

Parameter	Subject Device Portux CAD/CAM Disc (K192153) New Stetic S.A.	Primary Predicate Device Harvest Dental Polymer Blocks (K180578) Harvest Dental Products, LLC	Equivalence Discussion
Regulation Number	21 CFR 872.3770	21 CFR 872.3770	Substantially Equivalent
Regulatory Class	Class II	Class II	Substantially Equivalent
Product Code	EBG, EBI, MQC	EBG, EBI, MQC	Substantially Equivalent
Indication for Use	For the fabrication of crowns, bridges and structures for implant supported provisional removable denture and appliance prosthetics. - Provisional anterior and posterior crowns & bridges - Implant and abutment supported prosthetics. - Partial, complete and hybrid denture prosthetics (base and teeth) – Removable appliances (splint)	For the fabrication of crowns, bridges and structures for implant supported provisional removable denture and appliance prosthetics. - Provisional anterior and posterior crowns & bridges - Implant and abutment supported prosthetics. - Partial, complete and hybrid denture prosthetics (base and teeth) – Removable appliances (splint)	Substantially Equivalent
Technology	Blank for dental CAD/CAM	Blank for dental CAD/CAM	Substantially Equivalent
Material Shades	VITA-shades, clear, pink, red	VITA-shades, clear, pink	Substantially Equivalent
Material	PMMA	PMMA	Substantially Equivalent
Biocompatible	Yes	Yes	Substantially Equivalent
OTC or Rx	Rx	Rx	Substantially Equivalent
Sterile	Non-sterile	Non-sterile	Substantially Equivalent
Chemical Composition			
Base Material	Polymethyl methacrylate	Polymethyl methacrylate	Substantially Equivalent
Coloring Oxides	< 0.5%	< 1.1%	Substantially Equivalent
Physical Properties			
Performance Testing	ISO 10477 ISO 20795	ISO 10477 ISO 20795	Substantially Equivalent
Flexural Strength ISO 10477 ≥50 MPa ISO 20795 ≥65 MPa	> 65 MPa	> 90 MPa	Substantially Equivalent Slightly different values doesn't affect intended use of the device.
Flexural Modulus ISO 20795 ≥2000 MPa	> 2000 MPa	> 2200 MPa	Substantially Equivalent Slightly different values doesn't affect intended use of the device.
Water Absorption ISO 10477 ≤40 µg/mm ³ ISO 20795 ≤32 µg/mm ³	≤32 µg/mm ³	24 µg/mm ³	Substantially Equivalent Slightly different values doesn't affect intended use of the device.
Water Solubility ISO 10477 ≤7.5 µg/mm ³ ISO 20795 ≤1.6 µg/mm ³	≤1.6 µg/mm ³	0.0 µg/mm ³	Substantially Equivalent Slightly different values doesn't affect intended use of the device.
Residual monomer content ISO 20795 ≤2.2 %	≤2.2 %	< 1.1%	Substantially Equivalent Slightly different values doesn't affect intended use of the device.

Minor differences in material properties do not alter or impact the ability of the Subject device to be used for its intended use. In all cases, the Subject device meets the ISO 10477 and ISO 20795 material physical property requirements for these parameters. The Subject device is substantially equivalent to the Primary Predicate device with respect to Indications for Use and technological principles.

5.7 PERFORMANCE DATA

Physical property testing was performed on the Subject device to ISO 10477:2018, Dentistry – Polymer-based crown and veneering materials and ISO 20795-1:2013, Dentistry - Base polymers - Part 1: Denture base polymers. Results are stated in the Substantial Equivalence Comparison table above demonstrating the Subject device meets the property requirements of the referenced standards.

5.8 CLINICAL TESTING

The performance of PMMA as a provisional material in the clinical environment has been well established. No clinical testing was required to support substantial equivalence between the Subject and Primary Predicate devices. No clinical data is included in this submission.

5.9 BIOLOGICAL TESTING

The Subject device was evaluated to the Irritation and Sensitization Biocompatibility Endpoints according to ISO 10993-10:2010/(R)2013 and evaluated for Cytotoxicity according to ISO 10993-5:2009. Test results demonstrate suitable biocompatibility for the Subject device.

5.10 CONCLUSION

Overall, the Subject device has the following similarities to the legally marketed Primary Predicate device:

- Has the same Indications for Use
- Has the same Technological Characteristics
- Is fabricated from the same material (PMMA)
- Are both Prescription Use only
- Supplied as non-sterile

Therefore, the Portux CAD/CAM Disc Subject device is substantially equivalent to the Harvest Dental Polymer Blocks (K180578) Primary Predicate device.