March 9, 2020

ARUM Dentistry Co. Ltd
% Chris Brown
Manager
Aclivi, LLC
6455 Farley Road
Pinckney, Michigan 48169

Re: K193425
Trade/Device Name: Pre-Milled Blank
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: November 27, 2019
Received: December 10, 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.
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K193425

Device Name
Pre-Milled Blank

Indications for Use *(Describe)*

ARUM Dentistry's Pre-Milled Blank abutments are intended for attachment to dental implants in order to provide support for customized prosthetic restorations. Pre-Milled Blank abutments are indicated for screw-retained single restorations or cement-retained single or multi-unit restorations. The customized Pre-Milled Blank abutment will be attached to a dental implant using the included ARUM Dentistry prosthetic screw.

ARUM Dentistry's Pre-Milled Blanks are compatible with the implant systems listed in the Compatibility Table:

Compatibility Table

ARUM Pre-Milled Blank		Implant Platform compatibility	Restorative Platform diameter [mm]	Implant Body diameter [mm]	Abutment Screw
Ø10 mm	Ø14 mm				
CIHE037	CIHE038	NobelActive NP	3.5	3.5	CSTO001
CIHE039	CIHE040	NobelActive RP	3.9	4.3/5.0	CSTO002
CIHE135	CIHE136	NobelActive WP	5.1	5.5	

All digitally-designed Pre-Milled Blank abutments are intended to be sent to an ARUM Dentistry-validated milling center for manufacture.

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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K193425 - 510(k) Summary

ARUM Dentistry Co., Ltd.
Pre-Milled Blank
3/9/2020

5.1 ADMINISTRATIVE INFORMATION

Manufacturer Name	ARUM Dentistry Co., Ltd. 1 Building, 44, Techno 8-ro, Yuseong-gu, Daejeon, 34028 Republic of Korea Phone: +82-42-721-3644 Fax: +82-42-721-3645
Official Contact	Heung-Yeon Hwang, Quality Manager
Email:	hwanghy@arumdentistry.com

5.2 DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	Pre-Milled Blank
Common Name:	Abutment, Implant, Dental, Endosseous
Classification Name:	Endosseous dental implant abutment
Classification Regulation:	21 CFR 872.3630
Device Class:	Class II
Product Code:	NHA
Review Panel:	Dental Products Panel
Reviewing Branch:	Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices (OHT1) Dental Devices (DHT1B)

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 and reference devices:

Primary Predicate

510(k)	Device Name	Company Name
K190299	Elos Accurate Customized Abutment	Elos Medtech Pinol A/S

Reference Device

	Device Name	
K071370	NobelActive Internal Connection Implant	Nobel Biocare

5.4 DEVICE DESCRIPTION

ARUM Dentistry Co., Ltd.'s Pre-Milled Blank abutments are a system of dental implant abutments which have an implant /abutment interface design compatible with the Reference device OEM Nobel Biocare NobelActive implant system. Each Subject device implant abutment has a pre-manufactured implant interface connection interface with a customizable cylindrical section above the implant/abutment interface. The compatible implant body diameters range from 3.5 to 5.5 mm, with restorative interface diameters ranging from 3.0 to 5.1 mm (NP, RP and WP diameters).

The Subject device abutments and corresponding abutment screws are all pre-manufactured from Ti-6Al-4V ELI (Grade 23) titanium conforming to ASTM F136 and provided non-sterile to the user.

The Subject device abutments are in two customizable-section diameters for each restorative interface

diameter (NP, RP, WP); 10 mm and 14 mm

The cylindrical section of the Subject device abutments are intended to be customized by means of CAD/CAM technology to provide basis or support for single or multiple tooth prosthetic restorations. All digitally designed custom abutments from titanium blank abutments are to be sent to an ARUM Dentistry Co., Ltd.-validated milling center for manufacture.

5.5 INDICATIONS FOR USE

ARUM Dentistry's Pre-Milled Blank abutments are intended for attachment to dental implants in order to provide support for customized prosthetic restorations. Pre-Milled Blank abutments are indicated for screw-retained single restorations or cement-retained single or multi-unit restorations. The customized Pre-Milled Blank abutment will be attached to a dental implant using the included ARUM Dentistry prosthetic screw.

ARUM Dentistry's Pre-Milled Blanks are compatible with the implant systems listed in the Compatibility Table:

Compatibility Table

ARUM Pre-Milled Blank		Implant Platform compatibility	Restorative Platform diameter [mm]	Implant Body diameter [mm]	Abutment Screw
Ø10 mm	Ø14 mm				
CIHE037	CIHE038	NobelActive NP	3.5	3.5	CSTO001
CIHE039	CIHE040	NobelActive RP	3.9	4.3/5.0	CSTO002
CIHE135	CIHE136	NobelActive WP	5.1	5.5	

All digitally-designed Pre-Milled Blank abutments are intended to be sent to an ARUM Dentistry-validated milling center for manufacture.

5.6 EQUIVALENCE TO MARKETED DEVICE

The Subject device is substantially equivalent to the predicate device 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.

Comparison of Indications for Use Statements

<table>
<tr><th>Device</th><th>Indications for Use Statement</th></tr>
<tr><td>Subject Device
Pre-Milled Blank
ARUM Dentistry Co., LTD</td><td>
ARUM Dentistry's Pre-Milled Blank abutments are intended for attachment to dental implants in order to provide support for customized prosthetic restorations. Pre-Milled Blank abutments are indicated for screw-retained single restorations or cement-retained single or multi-unit restorations. The customized Pre-Milled Blank abutment will be attached to a dental implant using the included ARUM Dentistry prosthetic screw.

ARUM Dentistry's Pre-Milled Blanks are compatible with the implant systems listed in the Compatibility Table:

Compatibility Table
<table>
<tr><th colspan="2">ARUM Pre-Milled Blank</th><th rowspan="2">Implant Platform compatibility</th><th rowspan="2">Restorative Platform diameter [mm]</th><th rowspan="2">Implant Body diameter [mm]</th><th rowspan="2">Abutment Screw</th></tr>
<tr><th>Ø10 mm</th><th>Ø14 mm</th></tr>
<tr><td>CIHE037</td><td>CIHE038</td><td>NobelActive NP</td><td>3.5</td><td>3.5</td><td>CSTO001</td></tr>
<tr><td>CIHE039</td><td>CIHE040</td><td>NobelActive RP</td><td>3.9</td><td>4.3/5.0</td><td rowspan="2">CSTO002</td></tr>
<tr><td>CIHE135</td><td>CIHE136</td><td>NobelActive WP</td><td>5.1</td><td>5.5</td></tr>
</table>
All digitally-designed Pre-Milled Blank abutments are intended to be sent to an ARUM Dentistry-validated milling center for manufacture.
</td></tr>
<tr><td>Primary Predicate
Elos Accurate Customized Abutment (K190299)</td><td>
The Elos Accurate® Customized Abutments are intended for attaching to dental implants in order to provide basis for single or multiple tooth prosthetic restorations. The Elos Accurate® Customized Abutment will be attached to a dental implant using the included Elos Prosthetic screw.

The Elos Accurate® Customized Abutments are compatible with the implant systems listed in table 1:
Table 1.
</td></tr>
</table>

Device	Indications for Use Statement
Elos Medtech Pinol A/S	

Elos Accurate Customized Abutment – Model Type	Platform compatibility	Platform diameter [mm]	Implant Body diameter [mm]
AB-NBR35	Nobel Replace NP	3.5	3.5
AB-NBA30	Nobel CC 3.0	3.0	3.0
AB-NBA43	Nobel CC RP	3.9	4.3 & 4.5
AB-NBA60	Nobel CC WP	5.1	5.5
AB-SBO33	Straumann Bone Level NC	3.3	3.3
AB-SBO41	Straumann Bone Level RC	4.1 & 4.8	4.1 & 4.8

All digitally designed CAD/CAM customizations for the Elos Accurate® Customized Abutments are only intended to be sent and manufactured at a FDA registered Elos Medtech approved milling facility.

Except for the device name, reference/model numbers, the list of specific compatible platforms, and company approving the milling facility the Subject and Predicate devices have nearly identical Indications for Use. These differences do not change the intended use of the Subject and Predicate devices to provide support for single or multi-unit prosthetic restorations. The slight differences in the wording “attachment to dental implants in order to provide support for” and “attaching to dental implants in order to provide basis for” are simply different ways to describe the same intended use. The inclusion of the language “screw-retained single restoration and cement-retained single or multi-unit restoration” specifies sub-sets of the types of single and multi-unit restorations included in the primary predicate. Identifying the specific types of single and multi-unit restorations does not change the intended use of the device.

Comparison of Technological Characteristics

Design Parameter	**Subject Device** Pre-Milled Blanks ARUM Dentistry Co., Ltd	**Primary Predicate** Elos Accurate Customized Abutment (K190299)	Equivalence Discussion
FDA Classification & Product Code	Endosseous dental implant abutment, 21 CFR 872.360, NHA	Endosseous dental implant abutment, 21 CFR 872.360, NHA	***Substantially Equivalent***
Materials	Titanium Ti-6Al-4V ELI	Titanium Ti-6Al-4V ELI	***Substantially Equivalent***
Surface Finish	Non-coated	Non-coated Optional DLC coating on screws	***Substantially Equivalent*** The optional coating does not change the intended use of the device.
Implant Interface	Indexed	Indexed	***Substantially Equivalent***
Connection type	Conical	Flat top and conical	***Substantially Equivalent*** Different connection interfaces do not change the intended use of the device.
Abutment Interface diameter	3.5-5.1 mm	3.0-6.0 mm	***Substantially Equivalent*** Slight differences in interface diameters do not change the intended use of the device.
Prosthesis Attachment	Cement-retained	Cement-retained	***Substantially Equivalent***
Restoration	Single-unit & Multi-Unit	Single-unit & Multi-Unit	***Substantially Equivalent***
Mode of operation	Provide support for single and multi-unit prostheses.	Provide support for single and multi-unit prostheses.	***Substantially Equivalent***
Sterility	Provided non-sterile	Provided non-sterile	***Substantially Equivalent***
Sterilization method	Steam Sterilization	Steam sterilization	***Substantially Equivalent***
Abutment Design Parameters	Minimum wall thickness: 0.5 mm Maximum post height: 13 mm Maximum angulation: 30° Maximum diameter: 14 mm Minimum post height: 4 mm Minimum gingiva height: 0.5 mm Maximum gingiva height: 4 mm	Minimum wall thickness: 0.4 mm Maximum post height: 13 mm Maximum angulation: 30° Maximum diameter: 12 mm Minimum post height: 4 mm Minimum gingiva height: 0.5 mm Maximum gingiva height: 5mm	***Substantially Equivalent*** A slightly larger minimum wall thickness, and slightly smaller maximum gingival height of the Subject device does not change the intended use of the device.

Minor differences in abutment interface geometry due to compatible implant systems or restorative interface diameters do not introduce new risk nor change the intended use of the device to provide support for single and multi-unit prosthetic restorations.

Overall, the Technological Characteristics, mode of operation and materials of the Subject device are substantially equivalent to that of the Predicate device.

5.7 NON-CLINICAL PERFORMANCE DATA

Non-clinical performance data submitted to demonstrate substantial equivalence included: sterilization validation according to ISO 17665-1, ISO 17665-2, and ISO 14937; biocompatibility according to ISO 10993-5 and ANSI/AAMI ST72; reverse engineering of the OEM implant bodies, OEM abutments and OEM abutment screws to confirm compatibility; static and fatigue testing according to ISO 14801. No clinical data is included in this submission.

5.8 CONCLUSION

Slight variations in the wording of the Indications for Use statements for the Subject and Predicate devices do not change the intended use of the devices to provide support for single or multi-unit prosthetic restorations.

Slight differences in the compatible implant system abutments available in the Subject and Predicate device systems does not change the intended use of the devices to provide support for single or multi-unit prosthetic restorations.

The slight differences in the Technological Characteristics of the Subject and Predicate devices do not change the intended use of the devices to provide support for single or multi-unit prosthetic restorations or introduce new risk or concerns. Differences in Subject device abutment design parameters were validated with respect to intended use through Performance testing.

Overall, the Pre-Milled Blank Subject device is substantially equivalent to the Predicate device.