Dental Evolutions Inc.
% Raymond Kelly
Consultant
Arazy Group
3422 Leonardo Lane
New Smyrna Beach, Florida 32168

September 30, 2021

Re: K210523
Trade/Device Name: Implanova
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: June 8, 2021
Received: September 9, 2021

Dear Raymond Kelly:

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 Andrew 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)*
K210523

Device Name
Implanova

Indications for Use *(Describe)*

The Implanova® implants are intended for endosseous implantation in the mandible and maxilla for use as an artificial root structure. These root form implants can be used to replace single or multiple missing teeth and/or to support a fixed or removable prosthesis in partially or completely edentulous upper and lower dental arches. All devices in the Implanova® system including implant fixtures, abutments, healing caps, cover screws, and retention screws are intended for use by prescription only. Implanova® implants are intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Short implants (6mm) are intended for delayed loading.

All 3.0mm implants are indicated for the support and retention of fixed single tooth and fixed partial denture restorations in the mandibular central and lateral incisor and maxillary lateral incisor regions of partially edentulous jaws.

All 3.0mm implants must be splinted if two or more are used adjacent to each other. The 3.0mm implants (except 8mm length) are intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading. The 3.0mm implant with 8mm length is intended for delayed loading.

Implanova® All-in-One™ implants are indicated to be used when primary stability of the implant allows presence of an abutment at the time of placement. Implanova® All-in-One™ are immediately loaded by the presence of the abutment, but the occlusal forces need to be controlled and restricted while osseointergration takes place.

All Implanova® Bone Level implant fixtures are compatible with the straight type restorative components listed in the table below, including straight type abutments, straight type abutment screws and straight type temporary abutments that are intended to be on Astra Tech's OsseoSpeed™ TX 3.5S and OsseoSpeed™ TX 4.0S implant fixtures.

The Implanova® TiTACH™ system is indicated as a removable attachment of a full arch prosthesis when used in pairs and for a partial arch prosthesis in pairs. Minimum of two attachments are indicated per arch. Indicated to secure a complete or partial denture on 2-6 implants. This prosthesis is removable by patients.

The Implanova® FRIDGE® is indicated as a fixed attachment of a full arch prosthesis when used with 6 implants. This prosthesis is fixed for patients and removable by dentists.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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)*

K210523

Device Name
Implanova

Indications for Use *(Describe)*

Table 2- Implanova® Bone Level to Astra Tech Compatibility List

Component Type	Astra Tech Part #	Device Name	Manufacturer	Compatible Implanova® Bone Level Fixtures
Healing Abutment	22851	TempDesign™3.5/4.0	Astra Tech	All* Bone Level Implants
Healing Abutment	22853	TempDesign™3.5/4.0 NI	Astra Tech	All* Bone Level Implants
Healing Abutment	24281	Temporary Abutment 3.5/4.0	Astra Tech	All* Bone Level Implants
Healing Abutment	24280	Temporary Abutment 3.5/4.0 NI	Astra Tech	All* Bone Level Implants
Abutment Screw	24449	Abutment Screw Design 3.5/4.0	Astra Tech	All* Bone Level Implants
Abutment	24910 - 24916	Direct Abutment™3.5/4.0	Astra Tech	All* Bone Level Implants
Abutment	24917 - 24923	Direct Abutment API™3.5/4.0	Astra Tech	All* Bone Level Implants
Abutment	24893 - 24898	20° UniAbutment 3.5/4.0*	Astra Tech	All* Bone Level Implants
Abutment	24899 - 24904	45° UniAbutment 3.5/4.0*	Astra Tech	All* Bone Level Implants
Abutment	24905 - 24909	Ball Abutment 3.5/4.0	Astra Tech	All* Bone Level Implants
Abutment	24268 - 24272	Locator™ Abutment 3.5/4.0	Astra Tech	All* Bone Level Implants

***Implanova 3mm implants can be used only with straight abutments of compatible connections.**

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."