October 16, 2020

MEDENTiKA GmbH
% Jennifer Jackson
Director, Regulatory Affairs
Straumann USA, LLC
60 Minuteman Road
Andover, Massachusetts 01801

Re: K200906
Trade/Device Name: MINICONE Implant
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: September 15, 2020
Received: September 16, 2020

Dear Jennifer Jackson:

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,

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)*

K200906

Device Name:

MINICONE Implant

Indications for Use *(Describe)*

MINICONE are dental implants that are intended for the stabilization of removable dentures.

MINICONE Implants ø2.6 mm are suitable for oral endosteal implantation in the upper and lower jaw of fully or partially edentulous patients. The implants can be placed with immediate function when good primary stability is achieved. Furthermore, they are to be used in combination with the corresponding prosthetic Optiloc® matrix system and individual new or existing Optiloc® compatible overdentures or partial dentures.

For mandibular restorations, at least 4 MINICONE Implants should be placed.

For maxillary restorations, at least 6 MINICONE Implants should be placed.

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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5 510(k) Summary

5.1 Submitter's Contact Information

Submitter:	Straumann USA, LLC (on behalf of MEDENTiKA GmbH) 60 Minuteman Road Andover, MA 01810 Registration No.: 1222315 Owner/Operator No.: 9005052
Contact Person:	Jennifer M. Jackson, MS Director of Regulatory Affairs and Quality Phone Number: +1-978-747-2509 Fax Number: +1-978-747-0023 E-mail: jennifer.jackson@straumann.com
Prepared By & Alternate Contact:	Dr. Gerhard Polzer Head of Regulatory Affairs MEDENTiKA GmbH Phone number: +49 7229 6991216
Date of Submission:	October 14, 2020

5.2 Name of the Device

Trade Names:	MINICONE
Common Name:	Endosseous Dental Implant
Classification Name:	Endosseous Dental Implant
Regulation Number:	21 CFR 872.3640
Device Classification:	II
Product Code(s):	DZE
Review Branch:	Dental

5.3 Predicate Device(s)

Primary Predicate:

- K191895 – Straumann Mini implants

Reference Devices:

- K081653 – MDI MII One-piece Implant 2.9 mm
- K050705 – TiUnite Implants (Nobel Biocare)
- K180564 – Medentika Abutment System

5.4 Device Description

MINICONE consists of 2 MINICONE tapered implants with an external diameter of 2.6 mm and lengths of 10 and 12 mm, as well as related accessories.
The implants are manufactured utilizing Titanium Grade 5 ELI material (Ti-4Al-6V) and are finished with a roughened surface (sandblasted/acid etched). The implant neck is machined, and the attachment element of the implants is acting as a retention feature for dentures. This retention feature is coated using a Titanium Nitride (TiN) to obtain a more wear resistant surface and has the Optiloc® geometry which is connected to the denture. The roughened surface, implant neck, and retention feature are shown in Figure 1.

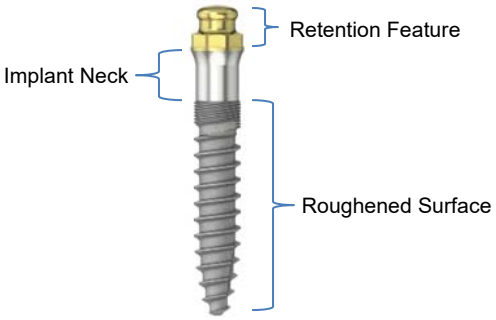

Figure 1 – MINICONE Implant

MINICONE Implants ø2.6mm are suitable for oral endosteal implantation in the upper and lower jaw of fully or partially edentulous patients.

The implants can be placed with immediate function when good primary stability is achieved. The MINICONE implants are intended for the stabilization of removable dentures. The removable dentures are connected to the MINICONE implants through the incorporated Optiloc® attachment element.

5.5 Intended Use

MINICONE Implants are intended for the stabilization of removable dentures.

5.6 Indications for Use

MINICONE are dental implants that are intended for the stabilization of removable dentures.

MINICONE Implants ∅2.6 mm are suitable for oral endosteal implantation in the upper and lower jaw of fully or partially edentulous patients. The implants can be placed with immediate function when good primary stability is achieved. Furthermore, they are to be used in combination with the corresponding prosthetic Optiloc® matrix system and individual new or existing Optiloc® compatible overdentures or partial dentures.

For mandibular restorations, at least 4 MINICONE Implants should be placed.

For maxillary restorations, at least 6 MINICONE Implants should be placed.

5.7 Technological Characteristics

The technological characteristics of the subject devices are compared to the primary predicate (K191895) and reference devices in Table 1. There are no significant changes related to the implant surface treatment, fundamental operating principles, sterilization processes or procedures between the subject devices and the predicate devices cleared under K191895. The subject implant diameter is 0.2 mm larger than the primary predicate device and the thread design of the subject implant incorporates a coronal micro-thread. Both devices are made of Titanium alloys, whereas MINICONE implants are manufactured from Titanium-6Aluminum-4Vanadium (Titanium Grade 5 ELI according to ASTM F136) and the reference devices from Titanium-Zirconium (Roxolid®). Furthermore, there is no difference regarding the Optiloc® attachment element incorporated on the top of the implants.

The reference predicate K180564 is included for reference to MRI compatibility. The reference device K081653 is included for reference to the implant material Titanium grade 5 ELI (Ti-6Al-4V). The reference device K050705 is included for reference to the machined collar of the implant which can be placed up to 1.5 mm subcrestally. The machined collar of the subject device can also be placed up to 1.5 mm subcrestally. The remaining 1.5 mm of the machined collar is intended for gingival support.

The Indications for Use of the subject device are similar to the Indications for Use of the primary predicate and reference devices, K191895 and K081653. The Indications for Use for K050705 includes single tooth restorations which is not applicable for the subject device. The Indications for Use are substantially equivalent.

K200906 – Traditional 510(k)

MINICONE

510(k) Summary

FEATURE	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE	REFERENCE DEVICE
K Number	K200906	K191895	K081653	K050705
Indications for Use	MINICONE Implants are intended for the stabilization of removable dentures. MINICONE Implants are suitable for oral endosteal implantation in the upper and lower jaw of fully or partially edentulous patients. The implants can be placed with immediate function when good primary stability is achieved. Furthermore, they are to be used in combination with the corresponding prosthetic Optiloc® matrix system and individual new or existing Optiloc® compatible overdentures or partial dentures. For mandibular restorations, at least 4 MINICONE Implants should be placed. For maxillary restorations, at least 6 MINICONE Implants should be placed.	STRAUMANN MINI IMPLANTS are intended for the stabilization of removable dentures. STRAUMANN MINI IMPLANTS are suitable for oral endosteal implantation in the upper and lower jaw of fully or partially edentulous patients. The implants can be placed with immediate function when good primary stability is achieved. Furthermore, they are to be used in combination with the corresponding prosthetic Optiloc® matrix system and individual new or existing Optiloc® compatible overdentures or partial dentures. For mandibular restorations, at least 4 STRAUMANN MINI IMPLANTS should be placed. For maxillary restorations, at least 6 STRAUMANN MINI IMPLANTS should be placed.	The MII Implant is intended to support single unit or multi-unit restorations in both long-term and temporary applications throughout the maxillary and mandibular arches. TheMII implant is indicated for immediate loading when good primary stability is achieved. Additionally, this device will permit stability and long-term fixation of upper and lower dentures in edentulous cases	Nobel Biocare TiUnite® Implants are root-form endosseous implants intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patient esthetics and chewing function. Nobel Biocare TiUnite® Implants are indicated for single or multiple unit restorations in splinted or non-splinted applications. Nobel Biocare TiUnite® Implants may be placed immediately and put into immediate function providing that the initial stability requirements detailed in the surgical manuals are satisfied. TiUnite® implants are indicated for use in soft bone whenever immediate or early loading is applied. The TiUnite® implants are preferred in these soft bone indications because bone formation is more rapid and greater than on machined surface implants resulting in better maintenance of initial implant stability, faster and stronger osseointegration, and higher success rates.
Implant Diameter	2.6 mm	2.4 mm	1.8 mm	3.5, 4.3, 5.0 and 6.0 mm
Design	One-piece implant	One-piece implant	One-piece implant	Two-piece implant
Implant Length	10 and 12 mm	10, 12, and 14 mm	10, 13, 15, and 18 mm	8, 10, 11.5, 13, and 16 mm
Material	Ti-6Al-4V (Titanium grade 5 ELI)	Ti- 15Zr (Roxolid)	Ti-6Al-4V	CP Titanium Grade 4
Retention Element Coating	TiN coated at the retention element	TiN coated at the retention element	TiN coated at the retention element	N/A

K200906 – Traditional 510(k)

MINICONE

510(k) Summary

FEATURE	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE	REFERENCE DEVICE
K Number	K200906	K191895	K081653	K050705
Endosseous Surface Treatment	Blasting and acid etching	SLA	Blasting and acid etching	TiUnite
Machined Collar	3 mm	N/A	N/A	0.75 and 1.5 mm
Abutment-to-restoration connection	Optiloc® geometry (Optimized Ball attachment element)	Optiloc geometry (Optimized ball attachment element)	O-Ball and tapered abutment design	Internal Tri-channel
Type of recommended restoration	Stabilization of removable dentures	Stabilization of removable dentures	Support of single-unit or multi-unit restorations for fixed and removable applications	Support of single-unit or multi-unit restorations for fixed and removable applications
Sterilization Method	Beta irradiation	Gamma irradiation	Gamma irradiation	Irradiation

Table 1 – Comparison of subject device versus predicate/reference devices

5.8 Performance Testing

Insertion torque testing and wear testing were conducted according to the FDA guidance document "*Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments"* and demonstrated the MINICONE implants are equivalent to the predicate and reference devices.

Wear testing is performed to evaluate the performance of the Optiloc® attachment element regarding its retention properties. The retention force loss of all Optiloc® matrices (white, yellow, green, blue, red, black ring) on MINICONE implants with 0°, 10° and 20° angulation passed the acceptance criteria and demonstrated substantial equivalence.

Fatigue testing of the MINICONE implants was conducted according to ISO 14801. The dynamic fatigue strength of the MINICONE implants demonstrated substantial equivalence.

No new issues of biocompatibility are raised for the subject devices. The titanium grade 5 ELI material and the TiN coating were previously cleared per K081653.

The sterilization process for the MINICONE implants was validated in accordance with ISO 11137-1:2006, *Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices, 2006-04-05*. The subject devices are cleaned, disinfected and sterilized via beta irradiation at a dose of 25 kGy (2.5 Mrad) minimum after packaging. A sterility assurance level (SAL) of 10^{-6} had been validated according to the standard cited above. The validation method used was the over kill bioburden method in accordance with ISO 11137-2:2013, *Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose*.

The subject devices are single use and are provided sterile. The shelf life is five years. Shelf life determination has been conducted in accelerated aging tests.

Conclusion

The documentation submitted in this premarket notification demonstrates the MINICONE implants are substantially equivalent to the primary predicate and reference devices.