



Food and Drug Administration
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August 21, 2014

ZL Microdent Attachment GmbH
Synnöve Lindeman
Head of Quality Management
Schutzenstrabe 6-8
Breckerfeld, DE D-58339

Re: K132585

Trade/Device Name: ZL Microdent Natural Lock Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseus Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: July 21, 2014
Received: July 24, 2014

Dear Ms. Lindeman:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number:

Device Name:

ZL Microdent NaturaLLock Implant System

Indications for use:

The NaturaLLock implant system is an endosseous dental implant system made of titanium. NaturaLLock implants are indicated for the support and retention of fixed single tooth and fixed partial denture restorations in the molar, premolar, cuspid, and incisor regions of partially edentulous jaws. NaturaLLock implants may be loaded immediately in the anterior mandibular arch if four are splinted together with a bar. NaturaLLock implants may be immediately restored with a temporary prosthesis that is not in functional occlusion.

The implants are offered in sterile condition, all other components can be sterilized in an autoclave .

Prescription Use AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of DCRH, Office of Device Evaluation (ODE)

Summary

510(k) Summary as required by section 807.92(c)

Date: 08/21/14

K-number: K133706

Submission Applicant:

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Trade name:

ZL Microdent NaturaLLock Implant System

Common name:

One-piece implant system

Classification name:

Endosseous dental implant, Dental (21 CFR 872.3640- DZE)

Predicate devices:

K031345 Nobel Direct

Nobel Biocare USA Inc., 22715 Savi Ranch Parkway, Yorba Linda, CA 92887, USA

K062281 Zimmer One Piece, 4,7mm

K052997 Zimmer Once Piece

Zimmer Dental Inc., 1900 Aston Ave., Carlsbad, CA 92008, USA

Substantial Equivalence Comparison Table

Relevant Areas	ZL Microdent – NaturaLLock implant system	Result	Nobel Biocare USA – Nobel Direct implant system	Zimmer Dental Inc. – One piece implant system
Intended Use Indications for use	The NaturaLLock implant system is an endosseous dental implant system made of titanium. NaturaLLock implants are indicated for the support and retention of fixed single tooth and fixed partial denture restorations in the molar, premolar, cuspid, and incisor regions of partially edentulous jaws. NaturaLLock implants may be loaded immediately in the anterior mandibular arch if four are splinted together with a bar. NaturaLLock implants may be immediately restored with a temporary prosthesis that is not in functional occlusion.	s.e.	The Nobel Biocare – Nobel Direct implant system is an endosseous dental implant system made of a material such as titanium or titanium alloy, that is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore a patient's chewing function.	The Zimmer) Dental One-Piece Implant is a one-piece endosseous dental implant which is a combination of implant and abutment sections. The implant is composed of titanium alloy. The abutment portion is pre-prepared and contoured for esthetic restoration. The abutment portion of the implant features a pre-prepared margin to facilitate the restoration process. The implant section is designed for ease of implantation and with greater surface area for osseointegration. The implant section surface is treated to facilitate osseointegration. In addition, the implant section is tapered with either double or triple-lead threads, depending upon the apical diameter.
Material	ZL Microdent NaturaLLock implants are made of Titanium	s.e.	Identical	Identical
Target population	Professional use only – qualified dental implantologists, oral surgeons or maxilla surgeons only. Strictly reserved to specialised and trained users.	s.e.	Identical	Identical
Where used	Dental practises	s.e.	Identical	Identical
Packaging	The NaturaLLock implant packaging comprises a non-sterile storage packaging with instructions for use (paper), a secondary packaging as a germ barrier and implant holding unit (glass) and a sterile primary packaging (glass) The glass container is delivered with a sticker showing all relevant information. Furthermore the storage packaging includes a sandwich tag for transference to the patient file (LOT No.)	s.e.	Similar	Similar

Relevant Areas	ZL Microdent – NaturaLLock implant system	Result	Nobel Biocare USA – Nobel Direct implant system	Zimmer Dental Inc. – One piece implant system
Performance / Biocompatibility	<p>Testing according ISO 10993 Biological Evaluation of Medical Devices applying all relevant provisions for the devices.</p> <p>All relevant testing regarding biocompatibility was carried out by ZL Micodent-Attachment GmbH & Co. KG with a total compliance with the provisions of ISO 10993. The same material is used for the predicate devices manufactured and distributed by Nobel Biocare USA and Leader Italia, which received market clearance and are in commercial distribution.</p>	s.e.	Identical	Identical
Sterilization	All implants are sold sterile. Drills, instruments and other invasive components are sold non sterile and need to be sterilized according to the manufacturers validated processing instructions. All components and instruments need to be sterilized prior to use.	s.e.	Identical	Identical
Sizes & Diameters	<p>ZL Microdent NaturaLLock implants and its components are available in the following lengths and diameters:</p> <p>Diameters & lengths: Ø 3.5 – lengths: 10, 13 & 16mm Ø 4.3 – lengths: 8, 10, 13 & 16mm Ø 5.0 – lengths: 8, 10, 13 & 16mm Ø 6.0 – lengths: 8, 10, 13 & 16mm</p>	s.e.	<p>Nobel Biocare Nobel Direct implants and its components are available in the following lengths and diameters:</p> <p>Diameter: Ø 3.0, 3.5, 4.3, 5.0 and 6.0mm Length: 8, 10, 13 and 16mm</p>	<p>Zimmer Once Piece Implants and its components are available in the following lengths and diameters:</p> <p>Diameter: Ø 3., 3.7 & 4.7mm Length: 10, 11.5, 13 and 16mm</p>

Description of the device:

The NaturaLLock single-stage implant for immediate restoration combines the endosteal and prosthetic implant sections in one piece (integrated abutment). The anatomically shaped implant has a self-tapping thread.

The NaturaLLock implant system includes single-stage implants, dental tools, instruments, drills, drill guide sleeves and a surgical tray, which contains a complete set of instruments structured according to the logical sequences of surgery.

The system is colour coded as follows: red Ø 3.5 mm, yellow Ø 4.3 mm, blue Ø 5.0 mm, green Ø 6.0 mm. The instruments are laser marked with the following information: drills: Ø and length, implant driver: Ø

Indication range:

For single and multiple tooth replacement in the upper and lower jaw. Adequate bone quality, width and height must be available. It has to be proven carefully, if the systemic state of the patient is adequate for an implantation, and especially if there are any allergic reactions on the implant components as well as any prohibitive diseases (e.g. diabetes, smoker).

Indications for Use:

The NaturaLLock implant system is an endosseous dental implant system made of titanium. NaturaLLock implants are indicated for the support and retention of fixed single tooth and fixed partial denture restorations in the molar, premolar, cuspid, and incisor regions of partially edentulous jaws. NaturaLLock implants may be loaded immediately in the anterior mandibular arch if four are splinted together with a bar. NaturaLLock implants may be immediately restored with a temporary prosthesis that is not in functional occlusion.

Comparison with predicate devices:

The ZL Microdent product is similar to the predicate devices in terms of technical characteristics, design, indications for use, target population, where it is used, performance, biocompatibility characteristics as well as sizes, surfaces and configurations. Similar as the Nobel and Zimmer predicate devices the ZL Microdent NaturaLLock implants are one-piece constructions, have an integral, pre-contoured abutment, a tapered implant body, a self-cutting thread and an implant head with symmetrical, axially directed grooves.

Conclusion: The ZL Microdent product can be deemed substantially equivalent for its indicated use.

Summary of the non-clinical testing data:

Results of risk analysis, case studies, cleanliness testing, biocompatibility, sterilization, cytotoxicity and packaging testing have demonstrated that ZL Microdent NaturaLLock implants are equivalent to the predicate device implants tested. When compared with predicate devices, results of bench performance testing indicated all acceptance criteria were met, and demonstrated the subject implants are equivalent. A series of safety and performance testing were performed to demonstrate that the ZL Microdent NaturaLLock implants do not raise any new issues of safety and efficacy.

Summary:

The presented data that was conducted on the ZL Microdent products, shows in its results and in comparison to the predicate devices substantially equivalence to the predicate devices for their intended use. The used materials are well researched.