510K Summary

APR 5 2013

Summary: K121281

Submitter: Company Address Simpler Implant Solutions Inc.
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V6J 3Y9

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Date of Preparation: 2013, April 4
Trade Name: SIMPLI™ Simpler Implant System
Common Name: Endosseous Dental Implant
Classification: Class II (Special Controls)
Product Code: DZE

The SIMPLI™ Simpler implant system is a threaded, endosseous dental implant designed to be one piece immediate load as well as delayed load to replace one, several or all missing teeth. It is equivalent (21 CFR 307.92 (a) (3) to a number of already legally marketed immediate load and delayed load devices.

The following Implants are predicates to the SIMPLI Simpler Dental Implant System

One Piece O Ring Abutment Implants:

Simpler Narrow Diameter	K083886

One Piece Crown and Bridge Abutment Implants:

IMTEC Sendax MDI	**K081653**
Bio Horizons Maestro	**K032351**
OCO Biomedical Mini	K080115

Overall, SIMPLI Simpler has the following similarities to the predicate devices:

- Same intended use
- Incorporates the same basic designs and materials
- Incorporates the same basic surface procedures
- Uses the same basic surgical protocols
- Has similar packaging materials and principles
- Sterilized requiring the same intended outcomes.

The difference lies in two areas:

1. The design of this implant system incorporates threads which are narrower than the predicates and increases available surface area.

2. The abutment portion has a slope on one side of the abutment at 25 degrees. This allows any two implants to be placed at a maximum of 50 degrees divergence from each

other and still be parallel thereby making it easier for impression taking when restoring the implants.

Indications for Use: The SIMPLI Simpler Implant System is indicated for use in surgical and restorative applications for placement of implants in the mandible and maxilla to provide support for prosthetic devices such as artificial teeth to provide chewing function to a patient with missing teeth. It is indicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

Bench Testing: We have bench tested prototypes of the SIMPLI Simpler implants to determine the amount of torque that can be placed on the implants during insertion. Tests indicate that up to 100NCm of torque can be applied without damage to the implant. No other testing has been performed except for the Fatigue tests performed on the predicate Simpler implants that verified the safety of the Implants and abutments.

Clinical Testing: No clinical testing has been performed on the SIMPLI Simpler system. The predicate device, the Simpler System, has been sold and used world wide for over 20 years without any recalls, law suits or non compliance issues. The SIMPLI Simpler Implant System is substantially equivalent to other commercially available Dental Implant Systems and is as safe and effective as the predicate devices.

Conclusions: I, Dr Harold Bergman, have personally placed over 10,000 predicate device Simpler implants in clinical practice and have found the system to be reliable and consistently successful when placed within accepted and recommended protocols. After carefully reviewing the literature, testing and examining the other predicate devices, I have every reason to believe the SIMPLI Simpler System will perform as well or better than any of the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 5, 2013

Dr. Harold Bergman
Simpler Implant Solutions, Incorporated
#404 1023 Wolfe Avenue
Vancouver, British Columbia V6H 1V6

Re: K121281
Trade/Device Name: SIMPLI Simpler Dental Implants
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: January 21, 2013
Received: March 20, 2013

Dear Dr. Bergman:

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,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: (if known): K121281

Device Name: SIMPLI Simpler Dental Implants

Indications for Use : The SIMPLI Simpler Implant System is indicated for use in surgical and restorative applications for placement of implants in the mandible and maxilla to provide support for prosthetic devices such as artificial teeth to provide chewing function to a patient with missing teeth. It is also indicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

Prescription Use __X_____ and/or Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D (21 CFR 801 Subpart C)

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Susan Runner, DDS, MA

Mary S. Runner -S
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(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K121281