SUMMARY: 510k:K083886

THE MINI IMPLANT SYSTEM

MAR 2 3 2009

Traditional 510(k): Device Summary

Submitter: Dr. Harold Bergman, President
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Fax: 604 736 9747
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Contact: Dr. Harold Bergman

Trade Name: Simpler HA Mini Implants
Simpler Mini Implants
Common Name: Mini Implants.
Classification Name: Endosseous Dental Implants.

Legally marketed devices to which S.E. is claimed
K073645 Simpler Mini Implants
K974856 Simpler Threaded Implants
K031106 Imtec Sendax MDI and MDI Plus

Description:
The HA coated Simpler Mini Implants (K 083886) are identical to the Simpler Mini Implants (K073645) except for the addition of the HA coating to the threaded area of the implants. Natural dentition is composed of a subgingival root and a supragingival crown. For both coated and uncoated mini implants the root form implant designs tend to mimic this structure and transitional implants are no exception. The implant base and the abutment are all in one piece. They are 2.5mm in diameter with a choice of 10, 13 or 15 mm in length for both the Simpler Mini Implants and the Simpler HA mini implants.

For partial and complete edentulism, a retaining feature containing a rubber ring acts like a socket to receive the ball on the top of the implant. A soft liner is placed into the patient's denture to adapt around the ball portion of the implant to provide retention to the denture. When seated, the denture rests on the gum tissue.

Indications for Use
The Simpler Mini Implants (ID S3002-4) and the Simpler HA Mini Implants (ID S5002-4) are intended to provide long term intra-bony applications. They are designed for immediate loading. They may also be used for temporary support for partial and fully edentulous restoration in the mandible and maxillae. They may be used for full or partial edentulism and are used as an option for a minimally invasive surgical intervention.
Other implants with similar indications for use are:
Mini Drive-Lock TM Dental Implants
ITI Dental Implants K894593 K894595
IMTEC Sendax MDIs K031106
Nobel Biocare Branemark Implants
The Simpler HA Mini Implant and the Simpler Mini Implant is used in a clinical setting by a qualified dentist. It is expected that the dentist be familiar with placing narrow diameter implants. Patients have the advantage of immediate loading of their prostheses.

Contraindications:
Contraindications customary to the placement of any dental implant may be observed. These include, but are not limited to current local infection, vascular impairment, uncontrolled diabetes, chronic high doses of steroids, clotting disorders, current anticoagulant therapy, metabolic bone disease, and other metabolic or systemic disorders which will affect bone or wound healing. Excessive loading or placement of implants in inadequate bone may result in fracture.

Complications: Possible complications with any oral reconstructive surgery include infection, closure perforation, abscess formation, bone loss, pain soft tissue irregularities and additional complications associated with anesthesia and dental surgery.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 2009

Dr. Harold Bergman
President
659543 BC Limited
Simpler One Stop
404 – 1023 Wolfe Avenue
Vancouver, BC
CANADA V6H 1V6

Re: K083886
Trade/Device Name: Simpler Mini Implant & Simpler HA Mini Implant
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: January 29, 2009
Received: January 29, 2009

Dear Dr. Bergman:

This letter corrects our substantially equivalent letter of March 23, 2009.

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 (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.

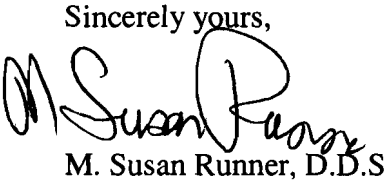
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



M. Susan Runner, D.D.S., M.A.
Acting Director
Divison of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS:

THE MINI IMPLANT SYSTEM

510(k) Number (if known): K083886

Device Name: Simpler Mini Implant & Simpler HA Mini Implant

Indications for Use:

The Simpler Mini Implants (ID SM3002-4) and the Simpler HA Mini Implants (ID SM5002-4) are intended to provide long term intra-bony applications. They are designed for immediate loading when there is good primary stability and an appropriate occlusal load. They may also be used for temporary support for partial and fully edentulous restoration in the mandible and maxilla. They may be used for full or partial edentulism and are used as an option to provide a minimally invasive surgical intervention.

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kevin Mulloy for MCR

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K 083886