1 of 2

K092674

3. SUMMARY

510(K) 092674

Dr. Harold Bergman, President
Pan Global Implant Corp.
Simpler Implants
#404 1023 Wolfe Ave.
Vancouver, BC
V6H 1V6
Phone: 604 736 9890 Fax: 604-736-9747
Contact: Karen Bergman. QA Assurance Officer or Dr. Bergman, President

DEC 2 8 2009

Trade Name: Simpler Toadstool Mini Implant & Simpler Toadstool HA Mini Implant Common Name: Simpler Toadstool Mini Implants & Simpler Toadstool Mini Implant
Classification: Endosseous Dental Implants

Legally marketed devices to which S.E. is claimed
K083886: Simpler Mini Implants
K031106 : Imtec Sendax MDI and MDI plus
K050586: Leone Implant System
K70601: Mini Drive-Lock Implant

Description The Simpler Toadstool Minis and the Simpler HA Toadstool Minis are Narrow Diameter implants. They are manufactured using 6/4 Titanium alloy 90% titanium 6% aluminum and 4% vanadium for strength. All implants are grit blasted and also acid etched and are available uncoated or coated with hydroxylapatite only on the threaded part of the implant. The diameter is 2.5mm and the lengths are 10mm, 13mm, 15 mm and 18 mm in both the coated and uncoated implants.
The implants are designed as one piece with a flattened toadstool shaped abutment with a hexagonal outline at the top of the implant. The flattened, hex ball fits into a keeper with a rubber o-ring placed in the prosthesis to reduce loading and to help with retention.

Intended Use: The Simpler Toadstool Mini Implant is intended to be used as an artificial root to provide immediate long term or transitional support for overdentures.
Indications for Use: The Simpler Toadstool Mini Implants and the Simpler HA Toadstool Mini Implants are intended to provide long term intra-bony applications for Soft Tissue Supported Over Dentures only. They are designed for immediate loading when there is good primary stability and an appropriate occlusal load. These implants may also be used for

temporary soft tissue overdenture support for partial and fully edentulous restoration in the mandible and maxilla. They may be used as a minimally invasive surgical technique option for full or partial edentuloism as an alternative to more invasive surgery involving conventional implants

Contraindications: Contraindications customary to the placement of any dental implants 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.

Summary of Testing: Simpler Toadstool Mini Implants do not introduce new issues for materials, surface treatment, fatigue testing and risk management that have not been addressed in all other approved Simpler Implants.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Dr. Harold Bergman
Chief Executive Officer
Pan Global Implant Corporation
#404 1023 wolfe Avenue
Vancouver, British Columbia
CANADA V6H 1V6

DEC 2 8 2009

Re: K092674
Trade/Device Name: Simpler Toadstool Mini Implant, Simpler HA Toadstool Mini Implant
Regulation Number: 21CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: December 17, 2009
Received: December 22, 2009

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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K092674

510(k) K092674

Device Name: Simpler Toadstool Mini Implant
Simpler HA Toadstool Mini Implant

Indications for Use:

The Simpler Toadstool Mini Implants and the Simpler HA Toadstool Mini Implants are intended to provide long term intra-bony applications for Soft Tissue Supported Over Dentures only. They are designed for immediate loading when there is good primary stability and an minimal occlusal load. These implants may also be used for temporary soft tissue overdenture support for partial and fully edentulous restoration in the mandible and maxilla. They may be used as a minimally invasive surgical technique option for full or partial edentulism as an alternative to more invasive surgery involving conventional implants.

Prescription Use X AND/OR Over the Counter Use _____
Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K092674