K073645

510(K)SUMMARY

OCT 21 2008

SUBMITTER:

Submitted on behalf of:

Company Address: **659543BC Ltd.**
Simpler One Stop
#404 1023 Wolfe Ave.
Vancouver, BC
V6H 1V6

By:

Dr. Harold Bergman
604 736 9890 (Telephone)
604 736 9747 (Fax)

CONTACT PERSON: **Dr. Harold Bergman**
604 736 9890

DATE PREPARED: **Oct. 9, 2008**

TRADE NAME: **Simpler Mini Implants**

COMMON NAME **Narrow Diameter Implants**

CLASSIFICATION **Class II (Special Controls)**

CLASSIFICATION NAME: **Endosseous Dental Implant**

The legally marketed devices to which we are claiming equivalence (21 CFR 807.92 (a)(3) are:

Mini Drive-Lock Implant K 070601
Bicon K023705

DESCRIPTION OF THE DEVICE: This transitional implant is designed to serve as a provisional artificial root to provide immediate load support for permanent implants. They are manufactured using 6/4 Titanium alloy 90% titanium 6% aluminum and 4 % vanadium for strength. The implants are grit blasted . The diameter is 2.5mm and the Lengths are 10mm,(SM3002), 13mm (SM3003) and 15 mm (SM3004).

The implants are designed as one piece with a ball abutment on one end at the top of the implant. The ball fits into a rubber o-ring and keeper in the prosthesis which is designed for retention.

INDICATIONS FOR USE: The transitional implant is designed for temportary use in endentulous sites. The primary purpose is to provide provisional prosthetic device protection from premature loading during the healing period. They are used to support bridges and dentures. Additional uses are inter-radicular transitional applications, immediate splinting stability for full and partial edenturlism and using minimally invasive surgical interventions.
The target population is determined when there is inadequate bone for wider implants as well as for patients wishing immediate functional loading. The transitionals are to be used in a clinical site by a qualified dentist experienced in placing dental implants.

SUMMARY OF TESTING: Simpler transitional implants do not introduce new issues for testing from other Simpler implants for materials, surface treatment, fatigue testing and sterilization.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Dr. Harold Bergman
659543BC Limited
#404, 1023 Wolfe Avenue
Vancouver, BC
CANADA V6H 1V6

OCT 21 2008

Re: K073645
Trade/Device Name: Simpler Mini Dental Implants
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: October 10, 2008
Received: October 14, 2008

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.

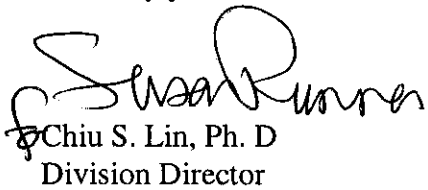
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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 postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,



Chiu S. Lin, Ph. D
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K073645

Device Name: Simpler Mini Dental Implants

Indications For Use:

INDICATIONS FOR USE:
The Transitional Implants are designed for temporary use in edentulous sites. The primary purpose is to provide provisional prosthetic devices to protect the permanent implants from premature loading during the healing period. They are used to support bridges and dentures.

Additional uses are inter-radicular transitional applications, immediate splinting stability, full and partial edentulism and using minimally invasive surgical interventions.

The target population is determined when there is inadequate bone for wider implants as well as for patients wishing immediate functional loading. The transitionals are to be used in a clinical site by a qualified dentist experienced in placing dental implants.

Prescription Use Yes 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)

Susan Runner

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

510(k) Number: K073645