APR 2 5 2006

Ms. Karen Bergman
Simpler Implant, Incorporated
404-1023 Wolfe Avenue
Vancouver, British Columbia V6H 1V6
Canada

Re: K060376
     Trade/Device Name: Simpler Threaded HA Coated, Models ST 5002-5016, Simpler T
     Regulation Number: 872.3640
     Regulation Name: Endosseous dental implant
     Regulatory Class: II
     Product Code: DZE
     Dated: April 11, 2006
     Received: April 13, 2006

Dear Ms. 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 (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); 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 continue 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 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

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

Enclosure

K060376

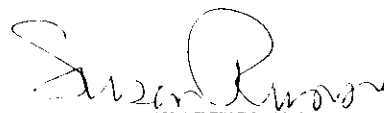## VI: INDICATIONS FOR USE

510(k) Number (if known)_____

Device Name Simpler HA Coated Threaded Dental Implants

Indications for Use:

The Simpler HA Coated Threaded Dental Implants are endosseous threaded implants used as an artificial root structure to replace missing teeth. They are used to support crowns, bridges. or dentures in the maxilla or mandible area of the mouth.

Please do not write below this line.

Concurrence of CDRH, Office of Device Evaluation(ODE)

(signature)

...iology, General Hospital,
...ntal Devices
4/25/06 - K06376

Prescription Use___yes___
Part 21 CFR 801 Subpart D)