K040714

APR - 9 2004

510(K) SUMMARY FOR THE INNOVA CORPORATION HYBRID ENDOPORE IMPLANT

Submitter's Name, Address, Telephone Number, And Contact Person

Innova LifeSciences Corporation
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Canada

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Date Prepared

February 25, 2004

Name of the Device

Hybrid Endopore® Endosseous Dental Implant System

Common or Usual Name

Endosseous Implant

Classification Name

Endosseous Implant (DZE)

Predicate Devices

Endopore® Endosseous Dental Implant System in 4.1 mm diameter (K926354) and 5.0 mm diameter (K971196); 5 mm long x 5.0 mm diameter Endopore Endosseous Dental Implant System (K032140).

Intended Use

The Endopore Implant is indicated for use in the upper or lower jaw arches to provide support for a dental prosthesis.

Principles of Operation

The principles of operation of the modified device are identical to the previously cleared Endopore Implant System except for the direct placement of the implant in the manner of a threaded-screw design.

Technological Characteristics

The technological characteristics of the modified Hybrid Endopore Implant also are identical to the predicates, except for the addition of three self-tapping threads in the coronal region of the implant. The dimensions of the modified Hybrid Endopore Implant, 9.5 mm and 11 mm in length x 4.0 mm diameter; and 7.5 mm and 9.5 mm in length x 5.0 mm diameter, are very similar to the dimensions of previously cleared Endopore implants.

Summary Basis for the Finding of Substantial Equivalence

The minor modification to the surface of the Endopore Implant does not alter its indications for use or its fundamental scientific technology. Therefore, the modified device is substantially equivalent to the predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 9 2004

Innova LifeSciences Corporation
Mr.Howard M. Holstein
C/O Mr. Hogan & Hartson L.L.P.
555 Thirteenth Street N.W.
Washington D.C. 20004

Re: K040714
Trade/Device Name: Hybrid Endopore® Endosseous Dental Implant System
Regulation Number: 872. 3640
Regulation Name: Endosseous Implant
Regulatory Class: III
Product Code: DZE
Dated: March 17, 2004
Received: March 18, 2004

Dear Mr. Holstein:

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.

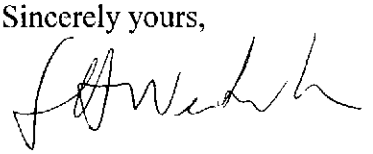
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Office of Compliance at (301) 594-5613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



for, 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

Indications for Use

510(k) Number (if known):

Device Name: Hybrid Endopore® Endosseous Dental Implant System

Indications For Use:

For use as an endosseous dental implant in the upper or lower jaw arches to provide support for prosthetic devices.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Dr Robert Beltz DDS for Dr. S Runner
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number: K040714