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K052951

510(K) SUMMARY FOR THE INNOVA LIFESCIENCES CORPORATION ENDOPORE® ANATOMIC ENDOSSEOUS DENTAL IMPLANT SYSTEM

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

Innova LifeSciences Corporation
60 Ironside Drive, Unit 3
Scarborough, Ontario M1X 1G4
Canada

Contact: Michael A. Kehoe, President
Telephone: (416) 340-8818
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Date Prepared

October 18, 2005

Name of the Device

Endopore® Anatomic Endosseous Dental Implant System

Common or Usual Name

Endosseous Implant and Abutment

Classification Name

Endosseous Implant (DZE); Endosseous Dental Implant Abutment (NHA)

Predicate Devices

Scalloped Endopore® Endosseous Dental Implant System (K043190); and Endopore® Endosseous Dental Implant System in lengths of 7, 9, or 12 mm with diameter of 4.1 mm (K926354); lengths of 7, 9, or 12 mm with diameter of 5 mm (K971196); and length of 5 mm length with diameter of 5 mm (032140).

Intended Use

ENDOPORE Anatomic dental implants may be used as artificial root components to support a prosthesis in an edentulous or partially edentulous mandible or maxilla.

ENDOPORE Anatomic dental implants are provided in three diameters, each intended for surgical placement into specific regions of the mandible and maxilla. **Diameters** and their corresponding **regions** are:

3.75 mm provided in lengths of 10, 12, and 15 mm for the **anterior mandible**

5.0 mm provided in lengths of 8.5, 10, 12, and 15 mm for the **anterior maxilla**, and

4.5 mm provided in lengths of 8.5, 10, 12, and 15 mm for both the **posterior mandible** and **posterior maxilla.**

The appropriate diameter of implant corresponding to the planned placement region should be selected. In addition, as with all dental implants, appropriate preoperative buccolingual width and crestal bone height measurements of the planned site should be made to ensure that adequate alveolar bone volume is available to accommodate the diameter and length of implant selected. If bone volume is not adequate, a press-fit ENDOPORE or threaded ENTEGRA implant of appropriate diameter and length may be considered for placement.

Principles of Operation

The principles of operation of the modified device are identical to those of the previously cleared Scalloped Endopore® Endosseous Dental Implant System (K043190).

Technological Characteristics

The technological characteristics of the modified Endopore® Anatomic Endosseous Dental Implant System also are identical to those of the predicates, except for the use of customized configurations to fit specific anatomic jaw locations, including the anterior mandible, anterior maxilla, posterior mandible and posterior maxilla, and the addition of concentric "steps" along the length of the implant's body. The dimensions of the Anatomic Implant System include diameters of 3.75 mm, 4.5 mm, and 5 mm and lengths of 8.5 mm, 10 mm, 12 mm, and 15 mm. These dimensions are within the range of those of the previously cleared Endopore® Endosseous Dental Implant System, with the addition of the 3.75 mm diameter and 15 mm length.

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Summary Basis for the Finding of Substantial Equivalence

The minor modification to the design of the Scalloped Endopore® Endosseous Dental Implant System and Endopore® Endosseous Dental Implant System does not alter the implant's indications for use or its fundamental scientific technology. Therefore, the modified device is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 27 2006

Innova Life Science Corporation
C/O Mr. Howard M. Holstein
Hogan & Hartson, LLP
555 Thirteenth Street, N.W.
Washington, DC 20004-1109

Re: K052951
Trade/Device Name: Endopore® Anatomic Endosseous Dental Implant System
Regulation Number: 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: November 28, 2005
Received: November 28, 2005

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 (240) 276-0115. 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/industry/support/index.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

Indications for Use

510(k) Number (if known): K052951

Device Name: Endopore® Anatomic Endosseous Dental Implant System

Indications for Use:

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Prescription Use __X__ AND/OR Over-The-Counter Use ____
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 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

[illegible], General Hospital,
Control, Dental Devices

510(k) K052951