

OCT - 2 2003

K032140

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

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

Innova LifeSciences Corporation
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Date Prepared

June 30, 2003

Name of the Device

5.0 x 5 mm 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);
Bud Industries, Inc. Dental Implant System 4 mm Length;
Bicon, Inc. 6.0 x 5.7 mm Dental Implant;
Cherchève Implant, 3.5 x 4 mm;
Branemark Integration AB Implant, 4.1 x 7 mm.

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. Like the predicate endosseous implants, the 5.0 x 5 mm Endopore Implant is inserted in a standard two-stage surgical procedure.

Technological Characteristics

The technological characteristics of the modified Endopore Implant also are identical to the predicate Endopore Implant System, except for the addition of a shorter implant length (5 mm) of the 5.0 mm diameter implant size. The device consists of the implant (root component), collar, collar retaining screw, coping, coping retaining screw, healing cap, and healing cap retaining screw. Alternatively, the overdenture abutment (with an overdenture abutment retaining screw) is available; this assembly incorporates the coping, coping retaining screw, collar, and collar retaining screw into a combined component for attachment to the root component. All of the component parts of the Endopore Implant are fabricated from a surgical grade (ASTM F 136-9) titanium-aluminum-vanadium (Ti₆Al₄V) alloy. The bone-contacting portion of the implant component has a powder-sintered porous coating of a surgical grade titanium-aluminum-vanadium alloy. The bone-contacting portion of the implant component is a truncated conical design with tapered sides.

Summary Basis for the Finding of Substantial Equivalence

The modification to the dimensions of the Endopore Implant does not alter its indications for use or its fundamental scientific technology. Furthermore, the new 5 mm implant length is within the range of lengths of other previously cleared and preamendments endosseous implants, which are available in lengths as short as 4 mm. Performance data included in the submission demonstrates that the shorter length does not adversely impact device performance. Therefore, the modified device is substantially equivalent to the predicates.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 2 2003

Innova Life Sciences Corporation
Mr. Howard M. Holstein
Regulatory Counsel
Hogan & Hartson, L.L.P.
555 13th Street N.W.
Washington, DC 20004

Re: K032140

Trade/Device Name: 5.0 x 5mm Endopore® Endosseous Dental Implant System
Regulation Number: 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: III
Product Code: DZE
Dated: July 11, 2003
Received: July 11, 2003

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) 594-4613. 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,



Susan Runner, DDS, MA

Interim 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 Statement

510(k) Number (if known): K032140

Device Name: 5.0 x 5 mm 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 a dental prosthesis.

Kevin Mulvey for HSR

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

510(k) Number: K032140

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 C.F.R. 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)