K021833

Dr. Albert Zickmann

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JUN 1 0 2002

510(K) Summary

General Information

Classification Name:	Endosseous Implant
Common Name:	Prosthetic Dental Implant System
Trade Name:	Blue Sky Bio Dental Implant System
Submitter's Name:	Blue Sky Bio
Address:	5455 N Sheridan Road, #3608 Chicago, IL 60640
Telephone:	773-769 2622
Fax:	773-878 8884
Contact:	Dr. Albert Zickmann
Date of Summary	May 2002

Device Description

The modification of the Blue Sky Bio Dental Implant System consists of root form dental implants of various lengths and diameters and associated abutment systems, which provide the clinician with cement retained and overdenture-type restorative options. Modifications to the existing system do not introduce new issues of safety or efficacy. The implants and components are supplied sterile or not sterile and are labeled accordingly. The system is suitable for a one-stage and two-stage protocol. The Implant system is not intended for immediate loading.

Intended Use

The Blue Sky Bio Dental Implant System is intended for use in either partially or fully edentulous mandibles and maxillae to give support to single or multiple units fixed dental prosthesis. It is also intended to give support to overdentures by means of o-ring abutments or bar-attachments.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 0 2002

Dr. Albert Zickmann
Blue Sky Bio
5455 N. Sheridan Road, # 3608
Chicago, Illinois 60640

Re: K021833
Trade/Device Name: Blue Sky Bio Dental Implant System
Regulation Number: 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: III
Product Code: DZE and NHA
Dated: May 20, 2002
Received: June 4, 2002

Dear Dr. Zickmann:

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 and additionally 21 CFR 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Dr. Albert Zickmann

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Indications for Use Statement

510(k) Number (if Known): K021833

Device Name: Blue Sky Bio Dental Implant System

Indications for Use:

- For Implantation into any area of the fully edentulous maxilla and mandible for the support of a removable or fixed dental prosthesis
- For Implantation into any area of the partially edentulous maxilla and mandible for the support of a removable or fixed dental prosthesis
- For single tooth or multiple unit prosthesis

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Divis
Divis Control,
and C Devices
510(k) K021833

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)