Blue Sky Bio, LLC

K060957

888 E BELVIDERE
SUITE 212
GRAYSLAKE, IL 60030
Tel: 718-376 0422
Fax: 888-234 3685
Email: azickmann@blueskybio.com

MAY - 5 2006

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, LLC
Address:	888 E Belvidere Rd., Suite 212 Grayslake, IL 60030
Telephone:	847-548 8499
Fax:	847-548 8491
Contact:	Michele Vovolka
Date of Summary	May 2005

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.

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. The system is suitable for a one-stage and two-stage protocol. Immediate placement and loading is indicated following certain restrictions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 5 2006

Dr. Albert Zickmann
Blue Sky Bio, LLC
888 East Belvidere, Suite 212
Grayslake, Illinois 60030

Re: K060957
Trade/Device Name: Blue Sky Bio Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: March 29, 2006
Received: April 7, 2006

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), 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

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Indications for Use Statement

510(k) Number (if Known): K060957

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
- For single stage or two stage surgical procedure
- One piece implants for single stage procedure only
- For immediate placement and immediate function when multiple units are splinted and for single units when adequate initial stability is achieved in type I or type II bone and under appropriate occlusal loading. Multiple units may be splinted with a bar. In edentulous cases restored with a fixed prosthesis, four or more implants must be used.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sun Kwon

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

510(k) Number K060957

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