K073713

MAR 28 2008

Blue Sky Bio, LLC

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

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	November 2007

Device Description

The modification of the Blue Sky Bio Dental Implant System consists of angled abutments and abutments to be custom milled to a specific angle to allow restoration of implants which are placed at an off-axis. A line of UCLA type straight abutments is introduced. In addition, an implant with a length of 8mm is introduced. A ceramic surgical osteotomy drill is also introduced.

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
- 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.
- Abutments are intended for use in conjunction with compatible Implant System in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit cement retained restoration.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 8 2008

Ms. Michele Vovolka
Blue Sky Bio, LLC
888 East Belvidere Road, Suite 212
Grayslake, Illinois 60030

Re: K073713
Trade/Device Name: Blue Sky Bio Dental Implant System
Regulation Number: 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: March 29, 2006
Received: December 31, 2007

Dear Ms. Vovolka:

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.

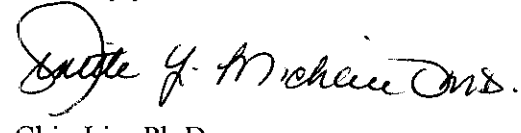
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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

Blue Sky Bio, LLC

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

Indications for Use Statement

510(k) Number (if Known): K073713

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
- 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.
- Abutments are intended for use in conjunction with compatible Implant System in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit cement retained restoration.

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

(Division Sign-Off) Concurrence of CDRH, Office of Device Evaluation (ODE)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K073713

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