K102034

Attachment 2

Blue Sky Bio, LLC

888 E BELVIDERE
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GRAYSLAKE, IL 60030
Tel: 718-376 0422
Fax: 888-234 3685

510(K) Summary

APR 19 2011

General Information

Classification Name:	Endosseous Implant
Common Name:	Prosthetic Dental Implant System
Product Code	DZE
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	June 2010

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 , screw retained and overdenture-type restorative options. The implants and abutments are made out of Ti6Al4V titanium alloy and have an internal anti-rotational geometry or have a one-piece design with the abutment portion being an integral part of the implant.
The device also includes exempt accessories such as laboratory analogs and drivers for insertion of the implants. and The activFluor surface treatment of the implants is the same as on Blue Sky Bio's predicate devices and is performed by blasting the surface and chemically etching to enhance the surface roughness for apposition of bone to the implant surface. The implants and components are supplied sterile or not sterile and are labeled accordingly.

Device Description Chart

Abutment Type	Platform	Angle deg.	Blue Sky Bio Predicate
Square Taper Angled	Regular, Wide	15	K073713
Square Taper Angled	Regular, Wide	25	K073713
Double Hex Angled	Narrow, Regular, Wide	15	K073713
Double Hex Angled	Narrow, Regular, Wide	25	K073713
Taper Hex Angled	Narrow, Regular, Wide	15	K073713
Taper Hex Angled	Narrow, Regular, Wide	30	K073713

Titanium alloy straight abutments	Platform	Predicate
Square Taper	Regular, Wide	K051507 , K060957
Double Hex	Narrow, Regular, Wide	K051507 , K060957
Taper Hex	Narrow, Regular, Wide	K051507 , K060957

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UCLA Abutments	Platform	BSB Predicate
Square Taper UCLA straight	Regular, Wide	K051507 , K060957
Double Hex UCLA straight	Narrow, Regular, Wide	K051507 , K060957
Taper Hex UCLA straight	Narrow, Regular, Wide	K051507 , K060957

Implant style	Diameter mm	Length	Blue Sky Bio Predicate	Predicate Size Range
Square Taper	3.3	8, 10, 12, 14, 16mm	K 051507, K060957	Ø 3.3mm-6mm; Length 8-16mm
Square Taper	3.3	8, 10, 12, 14, 16mm	K 051507, K060957	Ø 3.3mm-6mm; Length 8-16mm
Square Taper	4.1	8, 10, 12, 14, 16mm	K 051507, K060957	Ø 3.3mm-6mm; Length 8-16mm
Square Taper	4.8	8, 10, 12, 14, 16mm	K 051507, K060957	Ø 3.3mm-6mm; Length 8-16mm
Square Taper	5.6	8, 10, 12, 14, 16mm	K 051507, K060957	Ø 3.3mm-6mm; Length 8-16mm
Square Taper	7.0	8, 10, 12, 14, 16mm	K 051507, K060957	Ø 3.3mm-6mm; Length 8-16mm
Square Taper	8.0	8, 10, 12, 14, 16mm	K 051507, K060957	Ø 3.3mm-6mm; Length 8-16mm
Double Hex	3.25	9, 11, 13, 15, 17mm	K 051507, K060957	Ø 3.3mm-6mm; Length 8-16mm
Double Hex	3.5	9, 11, 13, 15, 17mm	K 051507, K060957	Ø 3.3mm-6mm; Length 8-16mm
Double Hex	4.0	9, 11, 13, 15, 17mm	K 051507, K060957	Ø 3.3mm-6mm; Length 8-16mm
Double Hex	5.0	9, 11, 13, 15, 17mm	K 051507, K060957	Ø 3.3mm-6mm; Length 8-16mm
Taper Hex	3.3	8, 10, 11.5, 13, 16mm	K 051507, K060957	Ø 3.3mm-6mm; Length 8-16mm
Taper Hex	4.3	8, 10, 11.5, 13, 16mm	K 051507, K060957	Ø 3.3mm-6mm; Length 8-16mm
Taper Hex	5.0	8, 10, 11.5, 13, 16mm	K 051507, K060957	Ø 3.3mm-6mm; Length 8-16mm
Internal Hex	3.25	10, 11.5, 13, 16mm	K 051507, K060957	Ø 3.3mm-4.8mm; Length 8-16mm
One Piece Implant	3.0	10, 12, 14mm	K051507	Ø 3.3mm-4.8mm; Length 8-16mm
One Piece Implant Overdenture	3.0	10, 12, 14mm	K051507	Ø 3.3mm-4.8mm; Length 8-16mm

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Short Implants	Diameter in mm	Length	Blue Sky Bio Predicate	Predicate Size Range
Square Taper	4.8	6mm	K073713	Ø 4.8-5,6mm; Length 6mm
Square Taper	5.6	6mm	K073713	Ø 4.8-5,6mm; Length 6mm
Square Taper	7.0	6mm	K073713	Ø 4.8-5,6mm; Length 6mm
Square Taper	8.0	6mm	K073713	Ø 4.8-5,6mm; Length 6mm

Intended Use for Two-Piece Implant Systems

- For implantation into any area of the fully 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.
- Unsplinted narrow implants and angled abutments are not to be used in the posterior areas.
- Taper Hex Implant System is compatible with NobelActive implants and prosthetics
- Double Hex Implant System is compatible with Astra double hex implants and prosthetics
- Square Taper Implant System is compatible with Straumann Bone-Level implants and prosthetics

Intended Use for One-Piece Implant System

- For implantation into any area of the fully edentulous maxilla and mandible for the support of a removable or fixed dental prosthesis
- For single tooth or multiple unit prosthesis
- For single 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. In edentulous cases four or more implants must be used
- Overdenture Implants are intended for support of removable prosthesis.

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Technological Characteristic Comparison Two Piece Systems

	Subject Device	Predicate Devices		
Feature	**Modified Blue Sky Bio Dental Implant System**	**Original Blue Sky Bio Dental Implant System K051507,K060957, K063874, K 73713**	**Nobel Biocare Dental Implant System K071370.**	**Straumann Implant System K062129**
Material (Implants, abutments, fixation screws, healing screws)	Titanium Alloy, Ti-6Al-4V	CP Titanium Grade 4, Ti-6Al-4V	CP Titanium	CP Titanium and Surgical Alloy
1 Stage/ 2 Stage	1 Stage and 2 Stage	1 Stage and 2 Stage	1 Stage and 2 Stage	1 Stage and 2 Stage
Surface	Blasted with resorbable medium, or Aluminum Oxide and Acid Etched	Blasted with resorbable medium, or Aluminum Oxide and Acid Etched	Proprietary galvanic process	Blasted with resorbable medium, and Acid Etched
Body Diameter (mm)	3.25 -5.0 Tapered & Straight and Tapered	3.3, 4.1, 4.3, 4.8, 5.0, 5.6 and 6.0 Tapered and Straight	3.5, 4.3, 5.0 Tapered & Straight	3.3 mm, 4.1mm and 4.8mm
Platform Diameter (mm)	3.25-5.0	3.5,4.1,4.3, 4.8, 5.0, 6.0, 6.5	3.5, 3.9	3mm, 3.7mm, 4.7mm
Lengths (mm)	6-16	6-16	10-15	8-16mm
External Screw Threads	Yes	Yes	Yes	Yes
Anti-rotational Feature	Internal Hex with taper, Internal Square with taper	Internal taper with , internal octagon, or Trilobe	Internal Hex with taper	Internal Square with taper
Gamma Sterilized	Yes	Yes	Yes	Yes
Two-Piece Screwed Abutment	Yes	Yes	Yes	Yes
Overdenture Abutment	Yes	Yes	Yes	Yes
Cover Screws, Healing abutments	Yes	Yes	Yes	Yes
Instruments (surgical and restorative)	Yes	Yes	Yes	Yes

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Technological Characteristic Comparison One Piece System

	Subject Device	Predicate Devices	
Feature	**Modified Blue Sky Bio Dental Implant System (One Piece)**	**Original Blue Sky Bio Dental Implant System K051507**	**Zimmer One-Piece Implant System K052997**
Material	Ti-6Al-4V	Ti-6Al-4V	Ti-6Al-4V
One Piece	Yes	Yes	Yes
Surface	Blasted with resorbable medium, or Aluminum Oxide and Acid Etched	Blasted with resorbable medium, or Aluminum Oxide and Acid Etched	Blasted with resorbable medium, and acid washed
Body Diameter (mm)	3.0mm	3.3 mm	3.0 mm, 3.7mm, 4.7mm
Externally Threaded Surface	Yes	Yes	Yes
Lengths (mm)	10, 12, 14 mm	10 -16 mm	10-16mm
Gamma Sterilized	Yes	Yes	Yes
Solid Abutment attached to implant for Cemented Restoration	Yes	Yes	Yes

Safety and Efficacy

The material, technology and facilities used to produce the modified Blue Sky Bio Dental Implant Systems are the same. Therefore it is substantially equivalent to other commercially available Dental Implant Systems including predicate devices Blue Sky Bio Dental Implant Systems(K051507, K060957, K063874, K073713), Nobel Biocare Dental Implant System (K071370), Zimmer Dental Dental Implant System (K052997) and Straumann Dental Implant System (K062129).
The technical comparison charts in Tab 5 list the primary technical aspects and specifications that are pertinent to Dental Implant Systems. The Blue Sky Bio dental implant system is as safe and effective as the predicate devices.

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Performance Tests

Compatibility tests with other systems according to Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document; Root-form Endosseous Dental Implants and Endosseous Dental Abutments: These tests were performed to assess compatibility with predicate devices. The tests showed that the new devices are compatible with predicate devices and the fit is adequate.

Fatigue testing for angled abutments and narrow diameter implants: This test has been conducted according to ISO 14801 for predicate devices. The new devices have larger wall thickness and equal or smaller angulation than the predicate devices and are therefore equivalent or stronger than the predicate devices.

Conclusion

The Blue Sky Bio Dental Implant system, subject to this submission and the predicate devices are believed to be substantially equivalent. The device constitutes a safe, reliable and effective medical device, meeting all declared requirements of its intended use and the device does not introduce new risks and does not present any adverse health effects or safety risks to patients when used as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Dr. Albert Zickmann
Bule Sky Bio, LLC
888 E Belvidere Road, Suite 212
Grayslake, Illinois 60030

APR 19 2011

Re: K102034
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, NHA
Dated: April 1, 2011
Received: April 11, 2011

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
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): K102034

Device Name: Blue Sky Bio Dental Implant System

Indications for Use:

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- Overdenture Implants are intended for support of removable prosthesis.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K102034