From: Massey, Cherryace * [Cherryace.Massey@fda.hhs.gov]
Sent: 10/22/2015 7:56:24 PM
To: kthomas@paxmed.com
CC: DCCLetters [DCCLetters@fda.hhs.gov]
Subject: K153064 ACK LETTER
Attachments: Acknowledgment%20Letter.pdf

2nd email

Acknowledgment Letter

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

10/22/2015

Kevin A Thomas
Regulatory Affairs
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, CA 92130
United States

Dear Kevin A Thomas:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. Please refer prominently to this number in all future correspondence that relates to this submission. Failure to do so may result in processing delays. If the 'Applicant' identified below is incorrect, please notify the 510(k) Staff immediately at (301) 796-5640.

Submission Number: K153064
Received: 10/22/2015
Applicant: BLUE SKY BIO, LLC
Device: Blue Sky Bio Zygomatic Impant System

We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

If any additional information is required, we will notify you via an Acceptance Review communication, Additional Information (AI) request, and/or Interactive Review communication. For additional information on these types of communication and their effect on the FDA Review Clock (if any), please refer to the following guidance documents:

"FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals" at http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm089735.htm.

"Refuse to Accept Policy for 510(k)s" at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf.

"Types of Communication During the Review of Medical Device Submissions" at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm341918.htm.

When responding to an information request that stops the FDA Review Clock (e.g., an AI request or refuse to accept (RTA) decision), you must submit your complete response with valid electronic copy (eCopy) to the Document Control Center (DCC) at the above address. An incomplete response or a response sent any other way (e.g., to another address or via email) will **not** be considered an official response and will not restart the FDA Review Clock. For more information about FDA's eCopy program, including the new technical standards for an eCopy, refer to the guidance document, "eCopy Program for Medical Device Submissions" at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf

To learn more about the overall 510(k) submission process, please refer to our website at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm.

If you have any procedural or policy questions, please refer to our website at http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm or contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041, (301) 796-7100, or *DICE@fda.hhs.gov*.

Sincerely yours,

Marjorie Shulman
Director, 510(k) Program
Premarket Notification (510(k)) Staff
Office of Device Evaluation
Center for Devices and Radiological Health

From: Sung, Charis * [Charis.Sung@fda.hhs.gov]
Sent: 11/6/2015 7:38:04 PM
To: lschulz@paxmed.com
CC: DCCLetters [DCCLetters@fda.hhs.gov]
Subject: K153064/S1 ACK LETTER
Attachments: K153064 S1.pdf

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Acknowledgment Letter

11/06/2015

Kevin A Thomas
Regulatory Affairs
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, CA 92130
United States

Dear Kevin A Thomas:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. Please refer prominently to this number in all future correspondence that relates to this submission. Failure to do so may result in processing delays. If the 'Applicant' identified below is incorrect, please notify the 510(k) Staff immediately at (301) 796-5640.

Submission Number: K153064/S001
Received: 11/06/2015
Applicant: BLUE SKY BIO, LLC
Device: Blue Sky Bio Zygomatic Implant System

We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

If any additional information is required, we will notify you via an Acceptance Review communication, Additional Information (AI) request, and/or Interactive Review communication. For additional information on these types of communication and their effect on the FDA Review Clock (if any), please refer to the following guidance documents:

"FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals" at http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm089735.htm.

"Refuse to Accept Policy for 510(k)s" at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf.

"Types of Communication During the Review of Medical Device Submissions" at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm341918.htm.

When responding to an information request that stops the FDA Review Clock (e.g., an AI request or refuse to accept (RTA) decision), you must submit your complete response with valid electronic copy (eCopy) to the Document Control Center (DCC) at the above address. An incomplete response or a response sent any other way (e.g., to another address or via email) will **not** be considered an official response and will not restart the FDA Review Clock. For more information about FDA's eCopy program, including the new technical standards for an eCopy, refer to the guidance document, "eCopy Program for Medical Device Submissions" at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf

To learn more about the overall 510(k) submission process, please refer to our website at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm.

If you have any procedural or policy questions, please refer to our website at http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm or contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041, (301) 796-7100, or *DICE@fda.hhs.gov*.

Sincerely yours,

Marjorie Shulman
Director, 510(k) Program
Premarket Notification (510(k)) Staff
Office of Device Evaluation
Center for Devices and Radiological Health

PAXMED INTERNATIONAL
Consulting Services in Medical Devices

Regulatory Affairs
Biomaterials
Clinical Trials
Quality Systems

November 5, 2015

Andrew Steen
U.S. Food and Drug Administration
Center for Devices and Radiological Heath
Document Control Center – W066-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: Refuse to Accept Response – K153064, Blue Sky Bio Zygomatic Implant System

Dear Mr. Steen:

Thank you for your review of the above referenced Premarket Notification. On behalf of Blue Sky Bio, LLC, we hereby submit this response request for additional information regarding the subject submission in conformance with the *Acceptance Checklist for Traditional 510(k)s* as conveyed in your email of November 4, 2015.

As directed in your email of today, November 5, we are submitting the information we sent by email yesterday. We are submitting:

the email to FDA sent November 4, 2015;
the revised subject device product list (attachment to email); and
the revised Instructions for Use (attachment to email).

This response is submitted as one paper copy and one eCopy on a CD. The eCopy is an exact duplicate of the paper copy.

Thank you for your review of this submission. If you need additional information, please contact me, Floyd Larson, or Linda Schulz at your earliest convenience.

Sincerely,

(b)(6)

Kevin A. Thomas, PhD
Vice President, Director of Regulatory Affairs

cc: Blue Sky Bio, LLC

Attachments:
1- Email to FDA sent November 4, 2015
2- Revised subject device product list
3- Revised Instructions for Use

PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130 USA
Tel 858 792-1235 • Fax 858 792-1236 • www.paxmed.com

Attachment 1

Email to FDA sent November 4, 2015

Kevin Thomas

From: Kevin Thomas
Sent: Wednesday, November 04, 2015 11:02
To: Andrew Steen (andrew.steen@fda.hhs.gov)
Cc: (b)(6) 'Linda K. Schulz (LSchulz@paxmed.com)'; 'Floyd Larson'
Subject: K153064, Blue Sky Bio Zygomatic Implant System
Attachments: K153064 (b)(4)

Dear Mr. Steen,

Thank you for your call yesterday regarding K153064, and for discussing the submission with Linda Schulz. Below is a summary of what was requested and response from the sponsor, Blue Sky Bio.

(b)(4)

Please let me know if this is sufficient to proceed with the substantive review or if you need any more information from us at this time.

Also, should we submit a hard copy via the Document Mail Center?

Thank you again for your assistance with this submission.

Best regards,

Kevin

Kevin A. Thomas, PhD
Vice President and Director of Regulatory Affairs
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, CA 92130

Phone 858-792-1235 (Ext. 309)
877-792-1235 (toll free In the US)

Fax 858-792-1236
Skype (b)(6)

www.paxmed.com
Consulting Services in Medical Devices
Biomaterials - Regulatory Affairs - Quality Systems - Clinical Research

Attachment 2

Revised subject device product list

(b)(4)

(b)(4)

Attachment 3

Revised Instructions for Use

(b)(4)

(b)(4)

(b)(4)

(b)(4)

K153064/S1

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November 5, 2015

FDA CDRH DMC
NOV 06 2015
Received

Andrew Steen
U.S. Food and Drug Administration
Center for Devices and Radiological Heath
Document Control Center – W066-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: Refuse to Accept Response – K153064, Blue Sky Bio Zygomatic Implant System

Dear Mr. Steen:

Thank you for your review of the above referenced Premarket Notification. On behalf of Blue Sky Bio, LLC, we hereby submit this response request for additional information regarding the subject submission in conformance with the *Acceptance Checklist for Traditional 510(k)s* as conveyed in your email of November 4, 2015.

As directed in your email of today, November 5, we are submitting the information we sent by email yesterday. We are submitting:

the email to FDA sent November 4, 2015;
the revised subject device product list (attachment to email); and
the revised Instructions for Use (attachment to email).

This response is submitted as one paper copy and one eCopy on a CD. The eCopy is an exact duplicate of the paper copy.

Thank you for your review of this submission. If you need additional information, please contact me, Floyd Larson, or Linda Schulz at your earliest convenience.

Sincerely,

(b)(6)

Kevin A. Thomas, PhD
Vice President, Director of Regulatory Affairs

cc: Blue Sky Bio, LLC

Attachments:
1- Email to FDA sent November 4, 2015
2- Revised subject device product list
3- Revised Instructions for Use

PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130 USA
Tel 858 792-1235 • Fax 858 792-1236 • www.paxmed.com

K153064 / 52

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March 31, 2016

Andrew I. Steen
U.S. Food and Drug Administration
Center for Devices and Radiological Heath
Document Control Center – W066-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: Additional Information – K153064, Blue Sky Bio Zygomatic Implant System

Dear Mr. Steen:

Thank you for your review of the above referenced Premarket Notification. On behalf of Blue Sky Bio, LLC, we hereby submit this response request for additional information regarding the subject submission as conveyed in your email of January 5, 2016.

This response is submitted as one paper copy and one eCopy on a CD. The eCopy is an exact duplicate of the paper copy.

FDA Deficiency

(b)(4)

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12264 El Camino Real, Suite 400
San Diego, California 92130 USA
Tel 1 858 792-1235 • Fax 1 858 792-1236 • www.paxmed.com

114

(b)(4)

(b)(4)

(b)(4)

Thank you for your review of this submission. If you need additional information, please contact me or Floyd Larson at your earliest convenience.

Sincerely,

(b)(6)

Kevin A. Thomas, PhD
Vice President, Director of Regulatory Affairs

cc: Blue Sky Bio, LLC

Attachments

(b)(4)

From: Sung, Charis * [Charis.Sung@fda.hhs.gov]
Sent: 3/31/2016 7:23:30 PM
To: kthomas@paxmed.com; lschulz@paxmed.com
CC: DCCLetters [DCCLetters@fda.hhs.gov]
Subject: K153064/S2 ACK LETTER
Attachments: K153064 S2.pdf

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Acknowledgment Letter

3/31/2016

Kevin A Thomas, Regulatory Affairs
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, CA 92130
UNITED STATES

Dear Kevin A Thomas:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the above letterhead address. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please notify the Program Operations Staff at (301) 796-5640.

Submission Number: K153064/S002
Received: 3/31/2016
Applicant: BLUE SKY BIO, LLC
Device: Blue Sky Bio Zygomatic Implant System

We will notify you when the review of this submission has been completed or if any additional information is required. For information about CDRH review regulations and policies, please refer to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm.

Sincerely yours,

Center for Devices and Radiological Health

From: Massey, Cherryace * [Cherryace.Massey@fda.hhs.gov]
Sent: 10/22/2015 7:57:15 PM
To: Kevin Thomas [kthomas@paxmed.com]
CC: DCCLetters [DCCLetters@fda.hhs.gov]; Floyd Larson [flarson@paxmed.com]; Claudia Fell [cfell@paxmed.com]
Subject: RE: K153064 ACK LETTER

Please disregard previous email; a corrected ACK letter has been sent.

From: Kevin Thomas [mailto:kthomas@paxmed.com]
Sent: Thursday, October 22, 2015 3:53 PM
To: Massey, Cherryace *
Cc: DCCLetters; Floyd Larson; Claudia Fell
Subject: Re: K153064 ACK LETTER

(b)(4)

Best regards,

Kevin

Kevin A. Thomas, PhD
Vice President and Director of Regulatory Affairs
PaxMed International, LLC
12264 El Camino Real, Suite 400

San Diego, CA 92130

Phone 858-792-1235 (Ext. 309)
877-792-1235 (toll free In the US)

Fax 858-792-1236
Skype **(b)(6)**

www.paxmed.com

Consulting Services in Medical Devices
Biomaterials - Regulatory Affairs - Quality Systems - Clinical Research

From: Massey, Cherryace * <Cherryace.Massey@fda.hhs.gov>
Sent: Thursday, October 22, 2015 11:45 AM
To: Kevin Thomas
Cc: DCCLetters
Subject: K153064 ACK LETTER

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Consulting Services in Medical Devices

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Biomaterials
Clinical Trials
Quality Systems

October 21, 2015

U.S. Food and Drug Administration
Center for Devices and Radiological Health (CDRH)
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

K153064

Re: Traditional 510(k) Premarket Notification for **Blue Sky Bio Zygomatic Implant System**

Dear Reviewers:

Pursuant to Section 510(k) of the Food, Drug and Cosmetics Act and 21 CFR Part 807, Blue Sky Bio, LLC hereby notifies FDA of its intent to introduce **Blue Sky Bio Zygomatic Implant System** into commercial distribution. On behalf of Blue Sky Bio, LLC, this Traditional 510(k) Premarket Notification is submitted as one paper copy and one eCopy on a CD. The eCopy is an exact duplicate of the paper copy.

There are no prior submissions for the subject device. Immediately following this letter is a copy of the *Acceptance Checklist for Traditional 510(k)s* indicating the location in the submission of the required information.

We believe the subject device is substantially equivalent, for the purpose of FDA's regulation of medical devices, to Class II medical devices cleared for marketing in the United States. The following data and information are supplied in conformance with 21 CFR 807.87.

ADMINISTRATIVE INFORMATION

Manufacturer Name	Blue Sky Bio, LLC 888 E Belvidere Road, Suite 212 Grayslake, IL 60030 Telephone +1 718-376-0422 Fax +1 888-234-3685
Official Contact	Michele Vovolka Vice President of RA/QA
Representative/Consultant	Kevin A. Thomas, PhD Linda K. Schulz, BSDH, RDH PaxMed International, LLC 12264 El Camino Real, Suite 400 San Diego, CA 92130 Telephone: +1 (858) 792-1235 Fax: +1 (858) 792-1236 Email: KThomas@paxmed.com LSchulz@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	Blue Sky Bio Zygomatic Implant System
Common Name	Endosseous dental implant Endosseous dental implant abutment
Classification Regulations	21 CFR 872.3640
Product Code	DZE NHA
Classification Panel	Dental Products Panel
Reviewing Branch	Dental Devices Branch

Design and Use of the Device

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?	NA	NA
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?	X	

Blue Sky Bio, LLC considers its intent to market this device as confidential commercial information and requests that this intent and the material contained herein be treated as trade secrets and confidential commercial information not available for disclosure under 21 CFR Part 20.

Please call me, Floyd Larson, Linda Schulz, or Christine Peterson if you have any questions regarding this submission.

Sincerely,

(b)(6)

Kevin A. Thomas, PhD
Vice President, Director of Regulatory Affairs

From: Sung, Charis * [Charis.Sung@fda.hhs.gov]
Sent: 11/6/2015 7:36:22 PM
To: kthomas@paxmed.com
CC: DCCLetters [DCCLetters@fda.hhs.gov]
Subject: K153064/S1 ACK LETTER
Attachments: K153064 S1.pdf

Traditional 510(k) Premarket Notification

Blue Sky Bio Zygomatic Implant System

Blue Sky Bio, LLC
888 E Belvidere Road, Suite 212
Grayslake, IL 60030
Telephone +1 718-376-0422
Fax +1 888-234-3685

CONTENTS

1. Medical Device User Fee Cover Sheet

Form Approved: OMB No. 0910-0511 Expiration Date: April 30, 2016 See Instructions for OMB Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION **MEDICAL DEVICE USER FEE COVER SHEET**	PAYMENT IDENTIFICATION NUMBER: (b)(4) Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)	2. CONTACT NAME
BLUE SKY BIO LLC 888 East Belvidere Rd Suite 212 Attn: Accumedix Grayslake IL 600630 US	Albert Zickmann 2.1 E-MAIL ADDRESS azickmann@blueskybio.com 2.2 TELEPHONE NUMBER (include Area code) 718-3760422 2.3 FACSIMILE (FAX) NUMBER (Include Area code)
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****8558	

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm

Select an application type:	3.1 Select a center
[X] Premarket notification(510(k)); except for third party	[X] CDRH
[ ] 513(g) Request for Information	[ ] CBER
[ ] Biologics License Application (BLA)	3.2 Select one of the types below
[ ] Premarket Approval Application (PMA)	[X] Original Application
[ ] Modular PMA	Supplement Types:
[ ] Product Development Protocol (PDP)	[ ] Efficacy (BLA)
[ ] Premarket Report (PMR)	[ ] Panel Track (PMA, PMR, PDP)
[ ] 30-Day Notice	[ ] Real-Time (PMA, PMR, PDP)
	[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

[X] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA	NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number: SBD168133

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?

[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)

[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates	[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).

[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT

Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 8455 Colesville Road, COLE-14-14253 Silver Spring, MD 20993-0002
[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b)(4) 15-Oct-2015

Form FDA 3601 (05/13)

"Close Window" Print Cover sheet

2. CDRH Premarket Review Submission Cover Sheet

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 9010-0120
Expiration Date: May 31, 2007.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number (if known)
October 21, 2015	(b)(4)	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA &HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☒ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
Blue Sky Bio, LLC.	3003402534		
Division Name *(if applicable)*	Phone Number *(including area code)*		
	+1 718-376-0422		
Street Address	FAX Number *(including area code)*		
888 E Belvidere Road, Suite 212	+1 888-234-3685		
City	State / Province	ZIP/Postal Code	Country
Grayslake	IL	60030	USA
Contact Name			
Michele Vovolka			
Contact Title	Contact E-mail Address		
V.P. of RA/QA	(b)(6)		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
PaxMed International, LLC			
Division Name *(if applicable)*	Phone Number *(including area code)*		
	+1 (858) 792-1235		
Street Address	FAX Number *(including area code)*		
12264 El Camino Real, Suite 400	+1 (858) 792-1236		
City	State / Province	ZIP/Postal Code	Country
San Diego	CA	92130	USA
Contact Name			
Kevin A. Thomas or Linda K. Schulz			
Contact Title	Contact E-mail Address		
Regulatory Affairs	KThomas@paxmed.com or LSchulz@paxmed.com		

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site
- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*
- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
- ☐ Process change:
  - ☐ Manufacturing
  - ☐ Sterilization
  - ☐ Packaging
  - ☐ Other *(specify below)*
- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*
- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment
- ☐ Response to FDA correspondence:
- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address
- ☐ Other Reason *(specify):*

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access
- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor
- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final
- ☐ Repose to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing
- ☐ Other Reason *(specify):*

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☒ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology
- ☐ Other Reason *(specify):*

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

DZE	NHA		

Summary of, or statement concerning, safety and effectiveness information

☒ 510 (k) summary attached
☐ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number	*Trade or Proprietary or Model Name*	*Manufacturer*
1	K141777	Neodent Implant System	JJGC Indústria e Comércio de Materiais Dentários SA
2	K102034	Blue Sky Bio Dental Implant System	Blue Sky Bio, LLC
3	K060957	Blue Sky Bio Dental Implant System	Blue Sky Bio, LLC
4	K093562	Zygomatic Implant System	Southern Implants, Inc.
5			
6			

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

Endosseous dental implant

	Trade or Proprietary or Model Name for This Device		Model Number
1	Blue Sky Bio Zygomatic Implant System	1	Various

FDA document numbers of all prior related submissions *(regardless of outcome)*

1 No prior submissions	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

☐ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
DZE, NHA	21 CFR 872.3640	☐ Class I ☒ Class II ☐ Class III ☐ Unclassified

Classification Panel

Dental Products Panel

Indications *(from labeling)*

Blue Sky Bio Zygomatic Implant System is indicated for surgical installation in the zygoma region, in cases of severe jaw resorption, in order to restore patient esthetics and chewing function. Blue Sky Bio zygomatic implants are recommended for the posterior (pre-molar/molar) region, one implant on each side, with at least two standard dental implants in the anterior region to support a fixed restoration. Blue Sky Bio zygomatic implants may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	FDA Establishment Registration Number	☒ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler

(b)(4)

☒ Original ☐ Add ☐ Delete	FDA Establishment Registration Number	☐ Manufacturer ☐ Contract Manufacturer	☒ Contract Sterilizer ☐ Repackager / Relabeler

(b)(4)

☐ Original ☐ Add ☐ Delete	FDA Establishment Registration Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler

Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)* ( )	
Street Address		FAX Number *(including area code)* ( )	
City		State / Province	ZIP/Postal Code / Country
Contact Name	Contact Title	Contact E-mail Address	

SECTION I	UTILIZATION OF STANDARDS				
Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.					
	Standards No.	Standards Organization	Standards Title	Version	Date
1	F136	ASTM	*Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)*	2013	2013
	Standards No.	Standards Organization	Standards Title	Version	Date
2	11137-1	ISO	*Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*	2006/ R 2010	2006/ R 2010
	Standards No.	Standards Organization	Standards Title	Version	Date
3	11137-2	ISO	*Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose*	2013	2013
	Standards No.	Standards Organization	Standards Title	Version	Date
4	17665-1	ISO	*Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices*	2006 /R 2013	2006 /R 2013
	Standards No.	Standards Organization	Standards Title	Version	Date
5	17665-2	ISO	*Sterilization of health care products – Moist heat – Part 2: Guidance on the application of ISO 17665-1*	2009	2009
	Standards No.	Standards Organization	Standards Title	Version	Date
6	F88	ASTM	*Standard Test Method for Seal Strength of Flexible Barrier Materials*	2009	2009
	Standards No.	Standards Organization	Standards Title	Version	Date
7	10993-1	AAMI / ANSI / ISO	*Biological evaluation of medical devices – Part 1: evaluation and testing within a risk management process*	2009/R 2013	2009/R 2013
	Standards No.	Standards Organization	Standards Title	Version	Date
8	14801	ISO	*Dentistry-Implants-Dynamic Fatigue Test for Endosseous Dental Implants*	2007	2007
Please include any additional standards to be cited on a separate page.					

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
CDRH (HFZ-342)
9200 Corporate Blvd.
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control

3. 510(k) Cover Letter and *Acceptance Checklist for Traditional 510(k)s*

PAXMED INTERNATIONAL
Consulting Services in Medical Devices

Regulatory Affairs
Biomaterials
Clinical Trials
Quality Systems

October 21, 2015

U.S. Food and Drug Administration
Center for Devices and Radiological Health (CDRH)
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: Traditional 510(k) Premarket Notification for **Blue Sky Bio Zygomatic Implant System**

Dear Reviewers:

Pursuant to Section 510(k) of the Food, Drug and Cosmetics Act and 21 CFR Part 807, Blue Sky Bio, LLC hereby notifies FDA of its intent to introduce **Blue Sky Bio Zygomatic Implant System** into commercial distribution. On behalf of Blue Sky Bio, LLC, this Traditional 510(k) Premarket Notification is submitted as one paper copy and one eCopy on a CD. The eCopy is an exact duplicate of the paper copy.

There are no prior submissions for the subject device. Immediately following this letter is a copy of the *Acceptance Checklist for Traditional 510(k)s* indicating the location in the submission of the required information.

We believe the subject device is substantially equivalent, for the purpose of FDA's regulation of medical devices, to Class II medical devices cleared for marketing in the United States. The following data and information are supplied in conformance with 21 CFR 807.87.

ADMINISTRATIVE INFORMATION

Manufacturer Name	Blue Sky Bio, LLC 888 E Belvidere Road, Suite 212 Grayslake, IL 60030 Telephone +1 718-376-0422 Fax +1 888-234-3685
Official Contact	Michele Vovolka Vice President of RA/QA
Representative/Consultant	Kevin A. Thomas, PhD Linda K. Schulz, BSDH, RDH PaxMed International, LLC 12264 El Camino Real, Suite 400 San Diego, CA 92130 Telephone: +1 (858) 792-1235 Fax: +1 (858) 792-1236 Email: KThomas@paxmed.com LSchulz@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	Blue Sky Bio Zygomatic Implant System
Common Name	Endosseous dental implant Endosseous dental implant abutment
Classification Regulations	21 CFR 872.3640
Product Code	DZE NHA
Classification Panel	Dental Products Panel
Reviewing Branch	Dental Devices Branch

Design and Use of the Device

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?	NA	NA
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?	X	

Blue Sky Bio, LLC considers its intent to market this device as confidential commercial information and requests that this intent and the material contained herein be treated as trade secrets and confidential commercial information not available for disclosure under 21 CFR Part 20.

Please call me, Floyd Larson, Linda Schulz, or Christine Peterson if you have any questions regarding this submission.

Sincerely,

(b)(6)

Kevin A. Thomas, PhD
Vice President, Director of Regulatory Affairs

Department of Health & Human Services
Food and Drug Administration

Center for Devices and Radiological Health
Office of Device Evaluation & Office of In-Vitro Diagnostics

Contains Nonbinding Recommendations

Print Form

Acceptance Checklist for Traditional 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.

510(k) #: Date Received by DCC:

Lead Reviewer:

Branch: DEDB Division: DAGRID Center/Office: CDRH/ODE

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete. It means the reviewer did not assess the element during RTA and the element will be assessed during the substantive review.

Preliminary Questions Answers in the shaded blocks indicate consultations with Center advisor is needed	Yes	No
1) Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)? If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Office Jurisdiction Liaison to determine the appropriate action, and inform division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If the product does not appear to be a device or such a combination product, mark "No."	X	
Comments?		
2. Is the application with the appropriate Center? If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the application is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or CBER Office Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If application should not be reviewed by your Center mark "No."	X	
Comments?		
3) If a Request for Designation was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following: a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission? b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission ? If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Jurisdictional Officer or appropriate CBER Jurisdiction Liaison to determine the appropriate action and inform your division management. Provide summary of Jurisdictional Officer's/Liaison's determination. If the answer to either question is no, mark "No." If there was no RFD, skip this question.		
Comments? No RFD		
4) Is this device type eligible for a 510(k) submission? If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), you should consult with the CDRH 510(k) Program Director or appropriate CBER staff during the acceptance review. If 510(k) is not the appropriate regulatory submission, mark "No."	X	
Comments?		

5) Is there a pending PMA for the same device with the same indications for use? If yes, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.		X
Comments?		
6) If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If yes, consult with the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM - BIMO) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action. Check on web at http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm		X
Comments? N/A		

If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and issue the "Original Jurisdictional Product" letter.
If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Jurisdictional Officer or CBER Office of Jurisdiction Liaison.
If the answer to 4 is "No," the lead reviewer should consult division management and other Center resources to determine the appropriate action.
If the answer to 5 is "Yes," then stop review of the 510(k), contact the CDRH 510(k) Staff and PMA Staff, or appropriate CBER staff.
If the answer to 6 is "Yes," then contact CDRH/OC/DBM-BIMO or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with the BIMO Staff, and indicate BIMO's recommendation/action.

Organizational Elements *Failure to include these items alone generally should not result in an RTA designation.*		
	Yes	No
1) Submission contains a Table of Contents	X	
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	X	
3) All pages of the submission are numbered.	X	
4) Type of 510(k) is identified (i.e., traditional, abbreviated, or special)	X	
Comments? 1) see pg 2 4) see cover page, CDRH Cover Sheet (Sec 2), Cover Letter (Sec 3)		

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed. **Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.** - Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
A. Administrative				
1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	X			
2) Submission identifies the following (such as in CDRH Premarket Review Submission Cover Sheet (Form 3514) or 510(k) cover letter):	X			X
a) Device trade name or proprietary name	X			
b) Device common name	X			
c) Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	X			
Comments? See Sec 2 and Sec 3 of the submission				
3) Submission contains Indications for Use Statement with Rx and/or OTC designation (see also 21 CFR 801.109).	X			X
Comments? See Sec 4 of the submission				
4) Submission contains 510(k) Summary or 510(k) Statement	X			X
a) Summary contains all elements per 21 CFR 807.92 *(See also* 510(k) Summary Checklist)	X			
b) Statement contains all elements per 21 CFR 807.93			X	
Comments? See Sec 5 of the submission				
5) Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k) *See recommended* format.	X			X
Comments? See Sec 6 of the submission				
6) Submission contains Class III Summary and Certification. *See recommended* content.			X	X
Comments? N/A - 510(k) is not a Class III submisison, see Sec 7 of the submission				
7) Submission contains clinical data			X	X
Comments? N/A - 510(k) does not contain clinical data, see Sec 8 and Sec 20 of the submission				
8) If submission references use of a national or international standard as part of demonstration of substantial equivalence, submission contains Standards Data Report for 510(k)s (Form 3654) or includes detailed information about how and the extent to which the standard has been followed.	X			X
Comments? See Sec 9 of the submission				
9) The submission identifies prior submissions for the same device for which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre-Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions for the subject device.	X			X

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed.				
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.				
- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	**Yes**	**No**	**N/A**	**Comment**
a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence outlined in prior communications are addressed. For additional information regarding the Pre-Submission process, please refer to the Draft Guidance "Medical Devices: The Pre-Submission Program and Meetings with FDA Staff." Once finalized, this guidance will represent the Agency's current thinking on this topic.			X	
Comments? N/A - no prior submissions for the same device, see Sec 2 and Sec 3				
B. Device Description				
10)				X
a) If there are requirements regarding the device description, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes device description information to establish that the submitter has followed the device-specific requirement.	X			
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes device description information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.	X			
Comments? See Sec 9 and Sec 11 of the submission; Description pp 64-66; Drawings pp 72-89				
11) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:				X
a) A description of the principle of operation and mechanism of action for achieving the intended effect.	X			
b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	X			
c) A list and description of each device for which clearance is requested.	X			
Comments? See Sec 11 and Sec 13 of the submission; Description pp 64-66; Product List pp 68-69				
12) Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions.	X			X
Comments? See Sec 11; Engineering drawings pp 72-89				
13) If device is intended to be marketed with multiple components, accessories, and/or as part of a system				X
a) Submission includes a list of all components and accessories to be marketed with the subject device.	X			
b) Submission includes a description (as detailed in item 11(a) and (b) and 12 above) of each component or accessory.	X			
c) A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance.			X	
Comments? See Sec 11 and Sec 13 of the submission; Description pp 64-66; Product List pp 68-69				

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed.				
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.				
- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	**Yes**	**No**	**N/A**	**Comment**
C. Substantial Equivalence Discussion				
14) Submitter has identified a predicate device.	X			X
a) Predicate's 510(k) number, trade name, and model number (if applicable) provided. For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding documenting preamendment status is available online.*	X			
b) The identified predicate(s) is consistent throughout the submission (i.e., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing.	X			
Comments? See Sec 2, Sec 5, and Sec 12 of the submission				
15) Submission includes a comparison of the following for the predicate(s) and subject device				X
a) Indications for Use	X			
b) Technology, including features, materials, and principles of operation	X			
Comments? See Sec 12 of the submission				
16) Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., does not constitute a new intended use; and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate), affect safety or effectiveness, or raise different questions of safety and effectiveness (see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f))	X			X
Comments? See Sec 12 of the submission				
D. Proposed Labeling (see also 21 CFR part 801)				
If *in vitro* diagnostic (IVD) device, criteria 17 & 19 may be omitted.				
17) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual) that include a description of the device, its intended use, and the directions for use.	X			X
a) Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided).	X			
b) Submission includes directions for use that - include statements of all conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) AND - includes directions for layperson (see 21 CFR 801.5) OR submission states that device qualifies for exemption per 21 CFR 801 Subpart D	X			
Comments? See Sec 4, Sec 5, and Sec 13 of the submission; 17 b 2 is not relevant as device is Rx only				
18) If indicated for prescription use, labeling includes the prescription use statement (see 21 CFR 801.109(b)(1)) or "Rx only" symbol [See also Alternative to Certain Prescription Device Labeling Requirements]	X			X

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed.				
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.				
- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	**Yes**	**No**	**N/A**	**Comment**
Comments? See Sec 13 of the submission				
19) General labeling provisions				X
a) Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1).	X			
b) Labeling includes device common or usual name. (21 CFR 801.61)			X	
Comments? See Sec 13 of the submission; device is for prescription use only				
20)				X
a) If there are requirements regarding labeling, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes labeling to establish that the submitter has followed the device-specific requirement.			X	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes labeling to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	
c) If there is a special controls document applicable to the device, the submission includes labeling to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.	X			
Comments? See Sec 13 of the submission				
21) If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10.			X	
E. Sterilization				
If IVD device and sterilization is not applicable, select "N/A" and criteria below will be omitted from checklist.				X
Submission states that the device and/or accessories are: (one of the below must be checked)				
X provided sterile				
X provided non-sterile but sterilized by the end user				
non-sterile when used				
Information regarding the sterility status of the device is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
Comments? See Sec 14 of the submission				
22) Assessment of the need for sterilization information				X

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed.				
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.				
- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	**Yes**	**No**	**N/A**	**Comment**
a) Identification of device, and/or accessories, and/or components that are provided sterile.	X			
b) Identification of device, and/or accessories, and/or components that are end user sterilized.	X			
c) Identification of device, and/or accessories, and/or components that are reusable and cleaning /disinfection instructions are provided.	X			
Comments? See Sec 14 of the submission				
23) If the device, and/or accessory, and/or a component is provided sterile:				
a) Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.).	X			
b) A description of method to validate the sterilization parameters (e.g., half-cycle method and full citation of FDA-recognized standard, including date) is provided for each proposed sterilization method. *Note, the sterilization validation report is not required.*	X			
c) For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant residuals remaining on the device and sterilant residual limits.			X	
d) Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package, Tyvek packaging, etc.)	X			
e) Sterility Assurance Level (SAL) is stated.	X			
24) If the device, and/or accessory, and/or a component is end user sterilized:				
a) Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.).	X			
b) A description of method to validate the sterilization parameters (e.g., half-cycle method and full citation of FDA-recognized standard, including date) is provided for each proposed sterilization method. *Note, the sterilization validation report is not required.*	X			
c) Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package, Tyvek packaging, etc.).	X			
d) Submission includes sterilization instructions for end user.	X			
25)				X
a) If there are requirements regarding sterility, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes sterility information to establish that the submitter has followed the device-specific requirement.			X	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes sterility information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed. Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. - Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
c) If there is a special controls document applicable to the device, the submission includes sterility information to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.	X			
Comments? See Sec 14 of the submission				
F. Shelf Life				
26) Proposed shelf life/expiration date stated			X	X
Comments? See Sec 14 of the submission				
27) For sterile device, submission includes summary of methods used to establish that device will remain sterile through the proposed shelf life or a rationale for why testing to establish shelf life is not applicable.			X	X
Comments? See Sec 14 of the submission				
28) Submission includes summary of methods used to establish that device performance is not adversely affected by aging or includes a rationale for why the storage conditions are not expected to affect device safety or effectiveness.	X			X
Comments? See Sec 14 of the submission				
G. Biocompatibility				
If IVD device, select "N/A" and the below criteria will be omitted from checklist.				X
Submission states that there: (one of the below must be checked)				
X are direct or indirect (e.g., through fluid infusion) patient-contacting components.				
are no direct or indirect (e.g., through fluid infusion) patient-contacting components.				
Information regarding the patient contact status of the device is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
Comments? See Sec 15 of the submission				
29) Submission includes list of patient-contacting device components and associated materials of construction, including identification of color additives, if present	X			X
Comments? See Sec 11 and Sec 15 of the submission				
30) Submission identifies contact classification (e.g., surface-contacting, less then 24 hour duration, etc.)	X			X
Comments? See Sec 15 of the submission				

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed. Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. - Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
31) Biocompatibility assessment of patient-contacting components Submission includes: Test protocol (including identification and description of test article), methods, pass/fail criteria, and results provided for each completed test, OR a statement that biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate).	X			X
Comments? See Sec 15 of the submission				
H. Software				X
Submission states that the device: (one of the below must be checked)				
does contain software/firmware.				
X does not contain software/firmware.				
Information regarding whether the device contains software is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
Comments? N/A - device does not contain software, see Sec 16 of the submission				
I. EMC and Electrical Safety				X
Submission states that the device: (one of the below must be checked)				
does require EMC and Electrical Safety evaluation.				
X does not require EMC and Electrical Safety evaluation.				
Information regarding whether the device requires EMC and Electrical Safety evaluation is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
Comments? N/A - device does not require EMS and Electrical Safety evaluation, see Sec 17 of the submission				
J. Performance Data - General If IVD device, select "N/A" and the below criteria will be omitted from checklist. Performance data criteria relating to IVD devices will be addressed in Section K.				
36) Full test report is provided for each completed test. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre-defined pass/fail criteria, results summary, conclusions, and an explanation of how the data generated from the test supports a finding of substantial equivalence.	X			X
Comments? See Sec 18 of the submission				
37)				X

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed.				
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.				
- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	**Yes**	**No**	**N/A**	**Comment**
a) If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish that the submitter has followed the device-specific requirement.			X	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes performance data to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	
c) If there is a special controls document applicable to the device, the submission includes performance data to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.			X	
Comments? See Sec 18 of the submission				
38) If literature is referenced in the submission, submission includes:			X	X
Comments? N/A - 510(k) does not reference literature				
39) For each completed nonclinical (i.e., animal) study conducted			X	X
Comments? N/A - 510(k) does not include nonclinical (i.e., animal) study data, see Sec 19 of the submittion				
K. Performance Characteristics - In Vitro Diagnostic Devices Only **(Also see 21 CFR 809.10(b)(12))**				
Submission states that the device: (one of the below must be checked)				
is an in vitro diagnostic device.				
X is not an in vitro diagnostic device.				

4. Indications for Use Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

(b)(4)

5. 510(k) Summary

510(k) Summary

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

6. Truthful and Accurate Statement

Truthful and Accurate Statement

I certify that, in my capacity as Vice President of Product Development for Blue Sky Bio, LLC, I believe to the best of my knowledge, that all data and information submitted in this 510(k) Premarket Notification are truthful and accurate and that no material fact has been omitted.

(b)(6)

Albert Zickmann, DDS
Vice President of Product Development
Blue Sky Bio, LLC

10/20/2015

Date

7. Class III Summary and Certification

(Not applicable – submission is not a Class III 510(k))

8. Financial Certification or Disclosure Statement

(Not applicable – submission does not include clinical data)

9. Declarations of Conformity and Summary Reports

(Reference to Special Controls)

Declarations of Conformity and Summary Reports
(Reference to Special Controls)

Performance Standards

No performance standards applicable to the subject device have been established by FDA.

Guidance Documents

The subject device conforms to the requirements of the FDA Class II Special Control Guidance Document *Root Form Endosseous Dental Implants and Endosseous Dental Implant Abutments*, issued May 12, 2004.

FDA Blue Book Memorandum #G95-1 *Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing."*

Voluntary Standards

The subject device is being manufactured in conformance with the following voluntary standards:

ASTM F136 (2013) *Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)*

ISO 11137-1 (2006/R 2010) *Sterilization of health care products – Radiation – Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices*

ISO 11137-2 (2013) *Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose*

ISO 17665-1 (2006/R 2013) *Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices*

ISO/TS 17665-2 (2009) *Sterilization of health care products – Moist heat – Part 2: Guidance on the application of ISO 17665-1*

ASTM F88 (2009) *Standard Test Method for Seal Strength of Flexible Barrier Materials*

ISO 10993-1 (2009/R 2013) *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*

ISO 14801 (2007) *Dentistry – Implants – Dynamic fatigue test for endosseous dental implants*

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(K)S

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM F136-13, Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 8-377	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of the standard? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http:/www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ASTM F136-13, STANDARD SPECIFICATION FOR WROUGHT TITANIUM-6 ALUMINUM-4 VANADIUM ELI (EXTRA LOW INTERSTITIAL) ALLOY FOR SURGICAL IMPLANT APPLICATIONS (UNS R56401)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
ALL		☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

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1350 Piccard Drive
Rockville, MD 20850

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Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(K)S

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 11137-1:2006/(R) 2010, Sterilization of health care products - Radiation - Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 14-461	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of the standard? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: Updated 510(k) Sterility Review Guidance K90-1; Final Guidance for Industry and FDA

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http:/www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ISO 11137-1:2006/(R) 2010, STERILIZATION OF HEALTH CARE PRODUCTS - RADIATION - PART 1: REQUIREMENTS FOR DEVELOPMENT, VALIDATION, AND ROUTINE CONTROL OF A STERILIZATION PROCESS FOR MEDICAL DEVICES.

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
ALL		☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED*
N/A

DESCRIPTION
Summary of Conformance

JUSTIFICATION
Not required per FDA Guidance K90-1

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
ALL		☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED*
N/A

DESCRIPTION
Testing report

JUSTIFICATION
Not required per FDA Guidance K90-1

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
(b)(4)	(b)(4)	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*
(b)(4)

DESCRIPTION
(b)(4)

JUSTIFICATION
(b)(4)

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

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Department of Health and Human Services
Food and Drug Administration

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 11137-2:2013, Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose.

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 14-438	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of the standard? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: Updated 510(k) Sterility Review Guidance K90-1; Final Guidance for Industry and FDA

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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[6] The online search of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ISO 11137-2:2013, STERILIZATION OF HEALTH CARE PRODUCTS - RADIATION - PART 2: ESTABLISHING THE STERILIZATION DOSE.

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
ALL		☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*
N/A

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
(b)(4)	(b)(4)	☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED*
(b)(4)

DESCRIPTION
N/A

JUSTIFICATION
(b)(4)

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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Food and Drug Administration

STANDARDS DATA REPORT FOR 510(K)S

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 17665-1:2006/(R)2013, Sterilization of health care products -- Moist heat -- Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 14-261	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of the standard? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: Updated 510(k) Sterility Review Guidance K90-1; Guidance for Industry and FDA

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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[6] The online search of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ISO 17665-1:2006/(R)2013, STERILIZATION OF HEALTH CARE PRODUCTS -- MOIST HEAT -- PART 1: REQUIREMENTS FOR THE DEVELOPMENT, VALIDATION, AND ROUTINE CONTROL OF A STERILIZATION PROCESS FOR MEDICAL DEVICES

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
ALL		☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED*
N/A

DESCRIPTION
Summary of Conformance

JUSTIFICATION
Not required per FDA Guidance K90-1

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
ALL		☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED*
N/A

DESCRIPTION
Testing report

JUSTIFICATION
Not required per FDA Guidance K90-1

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
(b)(4)	(b)(4)	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*
(b)(4)

DESCRIPTION
(b)(4)

JUSTIFICATION
(b)(4)

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

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Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(K)S

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO/TS 17665-2:2009: Sterilization of health care products -- Moist heat -- Part 2: Guidance on the application of ISO 17665-1

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 14-376	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of the standard? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: NA

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http:/www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ISO/TS 17665-2:2009: STERILIZATION OF HEALTH CARE PRODUCTS -- MOIST HEAT -- PART 2: GUIDANCE ON THE APPLICATION OF ISO 17665-1

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED*
(b)(4)

DESCRIPTION

JUSTIFICATION
(b)(4)

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED*
(b)(4)

DESCRIPTION

JUSTIFICATION
Acceptance criteria is not applicable because it applies to ISO 17665-1 standard, not this guidance

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED*
(b)(4)

DESCRIPTION

JUSTIFICATION

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Food and Drug Administration

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]
ASTM F88/F88M-09, Standard Test Method For Seal Strength Of Flexible Barrier Materials

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3] # 14-283		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of the standard? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: AAMI TIR22:2007, Guidance for ANSI/AAMI/ISO 11607, Packaging for terminally sterilized medical devices - Part 1 and Part 2:2006

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http:/www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ASTM F88/F88M-09, STANDARD TEST METHOD FOR SEAL STRENGTH OF FLEXIBLE BARRIER MATERIALS

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
(b)(4)	(b)(4)	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*
(b)(4)

DESCRIPTION
(b)(4)

JUSTIFICATION
(b)(4)

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

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Food and Drug Administration

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 10993-1:2009/(R) 2013, Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3] # 2-156		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of the standard? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: FDA Blue Book Memorandum #G95-1 Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http:/www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
AAMI / ANSI / ISO 10993-1:2009/(R) 2013, BIOLOGICAL EVALUATION OF MEDICAL DEVICES -- PART 1: EVALUATION AND TESTING WITHIN A RISK MANAGEMENT PROCESS

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
(b)(4)	(b)(4)	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*
(b)(4)

DESCRIPTION

JUSTIFICATION
(b)(4)

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 14801 Dentistry - Implants - Dynamic fatigue test for endosseous dental implants

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 4-195	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of the standard? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

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[6] The online search of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ISO 14801 DENTISTRY - IMPLANTS - DYNAMIC FATIGUE TEST FOR ENDOSSEOUS DENTAL IMPLANTS

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
(b)(4)	(b)(4)	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*
(b)(4)

DESCRIPTION
(b)(4)

JUSTIFICATION
(b)(4)

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
(b)(4)	(b)(4)	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*
(b)(4)

DESCRIPTION
(b)(4)

JUSTIFICATION
(b)(4)

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

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10. Executive Summary

Executive Summary

The purpose of this submission is to obtain marketing clearance for new dental implants designed for placement into the zygomatic bone and new mating abutments for support of screw-retained overdenture prosthetic restorations.

Intended Use

Blue Sky Bio Zygomatic Implant System is indicated for surgical installation in the zygoma region, in cases of severe jaw resorption, in order to restore patient esthetics and chewing function. Blue Sky Bio zygomatic implants are recommended for the posterior (pre-molar/molar) region, one implant on each side, with at least two standard dental implants in the anterior region to support a fixed restoration. Blue Sky Bio zygomatic implants may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.

Design

This submission includes threaded root-form dental implants designed for placement into the zygomatic bone with either an internal hexagon abutment interface (with a 45° bevel), or a tapered internal hexagon abutment interface (with a 12° taper). (b)(4)

(b)(4)

The zygomatic implants are provided with a body diameter (maximum major diameter of the endosseous thread) of 3.5, 4.1, 4.3, 4.7, and 5.0 mm. For each implant the endosseous thread tapers at the apical portion of the implant. The zygomatic implants are provided in multiple overall threaded lengths ranging from 35 mm to (b)(4)

The subject zygomatic implants are very similar in design to endosseous dental implants from Blue Sky Bio cleared in K102034 and K060957, except for a slight change in the endosseous thread and the longer lengths appropriate for zygomatic placement.

The subject zygomatic implants are provided with the same grit-blasted and acid etched surface as used on the implants cleared in K102034 and K060957.

This submission includes abutments with an internal hexagon and tapered internal hexagon interfaces for connection to the subject zygomatic implants. The abutments are provided with platform diameters of 3.5, 4.3, and 4.5 mm, and angulation of 17° or 30°. All subject device abutments are for support of screw-retained overdenture prosthetic restorations. The abutment screws compatible with the subject device abutments were cleared in K102034 and K060957.

A complete subject device product list and corresponding engineering drawings are provided in Section 11 *Device Description and Engineering Drawings.*

Materials

The subject device zygomatic implants and abutments are made of titanium alloy conforming to ASTM F136 *Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401).* The previously cleared abutment screws also are made of material conforming to ASTM F136.

All of the Blue Sky Bio Zygomatic Implant System subject device components are manufactured from identical materials, in the identical facilities using the identical manufacturing processes as used for Blue Sky Bio cleared previously in K102034 and K060957.

Sterilization

All subject device zygomatic implants are provided sterilized by (b)(4)

All subject device abutments (and the corresponding previously cleared abutment screws) are provided nonsterile, to be sterilized by the end user using moist heat (autoclave). A moist heat sterilization cycle validated to a sterility assurance level (SAL) of 10^{-6} is described in Section 14 *Sterilization and Packaging.*

Blue Sky Bio Zygomatic Implant System is not represented to be (b)(4)

Packaging and Shelf Life

All subject device zygomatic implants are packaged as single units sealed in a plastic pouch with a peelable chevron seal, and each sealed pouch is then inserted into a single unit plastic envelope. All subject device abutments (and the corresponding previously cleared abutment screws) are packaged in single units sealed in an autoclavable pouch.

The sterile barrier shelf life for the subject device is (b)(4). Package integrity of the sterile barrier was evaluated by seal strength testing according to ASTM F88 *Standard Test Method for Seal Strength of Flexible Barrier Materials*, and by dye immersion testing.

The subject device implants and abutments are not adversely affected by aging because the subject device is made from Ti-6Al-4V, known to be stable in air at room temperature for an indefinite period of time.

Biocompatibility

The subject device is a permanent, tissue/bone implant device intended for more than (b)(4) of patient contact.

The subject device implants and abutments are made of titanium alloy conforming to ASTM F136, *Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)*. This titanium alloy is commonly used in endosseous dental implants and abutments, and is the same material used for the Blue Sky Bio components previously cleared in K102034 and K060957. The subject device zygomatic implants are provided with the same grit-blasted and acid etched surface as used on the implants cleared in K102034 and K060957.

All of the subject device components are manufactured in the same facilities using the same manufacturing processes as used for the Blue Sky Bio components previously cleared in K102034 and K060957. Therefore, no new biocompatibility testing has been performed, as the subject device is substantially equivalent to the predicate devices in K102034 and K060957 with regards to materials and processing.

Performance Testing – Bench

Mechanical testing was performed to ensure that the strength of the Blue Sky Bio Zygomatic Implant System is appropriate for its intended use. After determination of the worst case construct, static and dynamic testing were performed according to ISO 14801 *Dentistry - Implants - Dynamic fatigue test for endosseous dental implants.* For all testing, implants were fixed at a point 3 mm apical to the nominal bone level and the load was applied at the appropriate angle to the axis of the implant to result in 10° of undercorrection. Lateral constraint was avoided by using a point contact at the junction of the loading device and the actuator of the test machine, as recommended in ISO 14801.

(b)(4)

(b)(4) A complete test report is included in Section 18 *Performance Testing – Bench.*

Equivalence to Marketed Device

Blue Sky Bio, LLC submits the following information in this Premarket Notification to demonstrate, for the purposes of FDA's regulation of medical devices, the subject device is substantially equivalent in indications and design principles to the following legally marketed predicate devices:

K141777, Neodent Implant System, JJGC Indústria e Comércio de Materiais Dentários SA;

K102034, Blue Sky Bio Dental Implant System, Blue Sky Bio, LLC;

K060957, Blue Sky Bio Dental Implant System, Blue Sky Bio, LLC; and

K093562, Zygomatic Implant System, Southern Implants, Inc.

The primary predicate device is K141777. The reference predicate devices are K102034, K060957, and K093562.

The subject device and the primary predicate K141777 have substantially equivalent indications for use, including restoration of patient esthetics and chewing function, and immediate loading when used with standard dental implants placed in the anterior region to support a fixed restoration. The implants of the subject device and the predicate device K141777 have similar designs and dimensions, including lengths appropriate for zygomatic placement. The subject zygomatic implants are very similar in design to endosseous dental implants from Blue Sky Bio cleared in K102034 and K060957, except for a slight change in the endosseous thread and the longer lengths appropriate for zygomatic placement. The subject zygomatic implants are provided in a range of implant body diameters (maximum endosseous thread diameters) of 3.5 mm to 5.0 mm, the same as the predicate implants cleared in K102034 and K060957.

This submission includes abutments with an internal hexagon and tapered internal hexagon interfaces for connection to the subject zygomatic implants. The abutments are provided with platform diameters of 3.5, 4.3, and 4.5 mm, and angulation of 17° or 30°. The subject device abutments are substantially equivalent to the abutments cleared in K102034 and K060957 in terms of implant-abutment connections, platform diameters, angulation, and materials. The subject abutments are to be used with compatible abutment screws cleared in K102034 and K060957.

The subject device implants and abutments are made of titanium alloy conforming to ASTM F136 *Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)*, the same as these components cleared in K102034 and K060957. The endosseous surface finish of the subject device implants is the same as the predicate implants cleared in K102034 and K060957.

The subject device implants have similar packaging and are sterilized using the same materials and processes as described in K102034 and K060957. The subject device abutments are provided nonsterile in similar packaging and are to be sterilized using the same processes as described in K102034 and K060957.

Overall, the subject device has the following similarities to the predicate devices:

- has the same intended use,
- uses the same operating principle,
- incorporates the same basic design,
- incorporates the same or very similar materials, and
- has similar packaging and is sterilized using the same materials and processes.

The basis for the belief of Blue Sky Bio, LLC that the subject device is substantially equivalent to the predicate devices is summarized in the following *Table of Substantial Equivalence*.

Summary: Table of Substantial Equivalence

(b)(4)

11. Device Description and Engineering Drawings

Device Description

The purpose of this submission is to obtain marketing clearance for new dental implants designed for placement into the zygomatic bone and new mating abutments for support of screw-retained overdenture prosthetic restorations.

Subject Device Designs

This submission includes threaded root-form dental implants designed for placement into the zygomatic bone with either an internal hexagon abutment interface (with a 45° bevel), or a tapered internal hexagon abutment interface (with a 12° taper). (b)(4)

(b)(4)

The zygomatic implants are provided with a body diameter (maximum major diameter of the endosseous thread) of 3.5, 4.1, 4.3, 4.7, and 5.0 mm. For each implant the endosseous thread tapers at the apical portion of the implant. The zygomatic implants are provided in multiple overall threaded lengths ranging from 35 mm to (b)(4)

The subject zygomatic implants are very similar in design to endosseous dental implants from Blue Sky Bio cleared in K102034 and K060957, except for a slight change in the endosseous thread and the longer lengths appropriate for zygomatic placement.

The subject zygomatic implants are provided with the same grit-blasted and acid etched surface as used on the implants cleared in K102034 and K060957.

(b)(4)

This submission includes abutments with internal hexagon and tapered internal hexagon interfaces for connection to the subject zygomatic implants. The abutments are provided with platform diameters of 3.5, 4.3, and 4.5 mm, and angulation of 17° or 30°. All subject device abutments are for support of screw-retained overdenture prosthetic restorations. The implant connection portions of the internal hex abutments are anodized for easy determination of the platform (anodized green for 3.5 mm Ø platform, and anodized fuchsia for 4.5 mm Ø platform). Similarly, the implant connection portions of the tapered hex abutments are anodized magenta for the 3.5 mm Ø platform and anodized gold for the 4.3 mm Ø platform. The abutment screws compatible with the subject device abutments were cleared in K102034 and K060957.

Instruments and accessories used for placement of the Blue Sky Bio Zygomatic Implant System are not subjects of this Premarket Notification.

Material Composition

The subject device zygomatic implants and abutments are made of titanium alloy conforming to ASTM F136 *Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401).* The previously cleared abutment screws also are made of material conforming to ASTM F136.

All of the Blue Sky Bio Zygomatic Implant System subject device components are manufactured from identical materials, in the identical facilities using the identical manufacturing processes as used for Blue Sky Bio cleared previously in K102034 and K060957.

How Provided

(b)(4)

Product List and Engineering Drawings

A product list for the subject device components, including part numbers, product descriptions, and corresponding engineering drawing numbers, is included in this section. Also included in this section is a table showing the subject device implant-abutment compatibilities, and engineering drawings for each subject device.

Subject Device Product List

Subject Device Product List including Engineering Drawing Numbers

(b)(4)

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(b)(4)

Subject Device Engineering Drawings

(b)(4)

(b)(4)

(b)(4)

(b)(4)

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(b)(4)

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(b)(4)

(b)(4)

12. Substantial Equivalence Discussion

Substantial Equivalence Discussion

Blue Sky Bio, LLC submits the following information in this Premarket Notification to demonstrate, for the purposes of FDA's regulation of medical devices, the subject device is substantially equivalent in indications and design principles to the following legally marketed predicate devices:

K141777, Neodent Implant System, JJGC Indústria e Comércio de Materiais Dentários SA;

K102034, Blue Sky Bio Dental Implant System, Blue Sky Bio, LLC;

K060957, Blue Sky Bio Dental Implant System, Blue Sky Bio, LLC; and

K093562, Zygomatic Implant System, Southern Implants, Inc.

The primary predicate device is K141777. The reference predicate devices are K102034, K060957, and K093562.

The subject device and the primary predicate K141777 have substantially equivalent indications for use, including restoration of patient esthetics and chewing function, and immediate loading when used with standard dental implants placed in the anterior region to support a fixed restoration. The implants of the subject device and the predicate device K141777 have similar designs and dimensions, including lengths appropriate for zygomatic placement. The subject zygomatic implants are very similar in design to endosseous dental implants from Blue Sky Bio cleared in K102034 and K060957, except for a slight change in the endosseous thread and the longer lengths appropriate for zygomatic placement. The subject zygomatic implants are provided in a range of implant body diameters (maximum endosseous thread diameters) of 3.5 mm to 5.0 mm, the same as the predicate implants cleared in K102034 and K060957.

This submission includes abutments with an internal hexagon and tapered internal hexagon interfaces for connection to the subject zygomatic implants. The abutments are provided with platform diameters of 3.5, 4.3, and 4.5 mm, and angulation of 17° or 30°. The subject device abutments are substantially equivalent to the abutments cleared in K102034 and K060957 in terms of implant-abutment connections, platform diameters, angulation, and materials. The subject abutments are to be used with compatible abutment screws cleared in K102034 and K060957.

The subject device implants and abutments are made of titanium alloy conforming to ASTM F136 *Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)*, the same as these components cleared in K102034 and K060957. The endosseous surface finish of the subject device implants is the same as the predicate implants cleared in K102034 and K060957.

The subject device implants have similar packaging and are sterilized using the same materials and processes as described in K102034 and K060957. The subject device abutments are provided nonsterile in similar packaging and are to be sterilized using the same processes as described in K102034 and K060957.

Overall, the subject device has the following similarities to the predicate devices:

- has the same intended use,
- uses the same operating principle,
- incorporates the same basic design,
- incorporates the same or very similar materials, and
- has similar packaging and is sterilized using the same materials and processes.

The basis for the belief of Blue Sky Bio, LLC that the subject device is substantially equivalent to the predicate devices is summarized in the following *Table of Substantial Equivalence*.

Summary: Table of Substantial Equivalence

(b)(4)

Predicate Device Literature

JJGC Indústria e Comércio de Materiais Dentários SA

Neodent Implant System

K141777

Device Classification Name	Implant, Endosseous, Root-Form[23]
510(K) Number	K141777
Device Name	NEODENT IMPLANT SYSTEM
Applicant	JJGC INDUSTRIA E COMERCIO DE MATERIAIS DENTARIOS S 12264 El Camino Real, Ste 400 San Diego, CA 92130
Applicant Contact	Kevin A Thomas
Correspondent	JJGC INDUSTRIA E COMERCIO DE MATERIAIS DENTARIOS S 12264 El Camino Real, Ste 400 San Diego, CA 92130
Correspodent Contact	Kevin A Thomas
Regulation Number	872.3640[24]
Classification Product Code	DZE[25]
Subsequent Product Code	NHA[26]
Date Received	07/02/2014
Decision Date	07/20/2015
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	Dental
510k Review Panel	Dental
Summary	Summary[27]
Type	Traditional
Reviewed By Third Party	No
Combination Product	No

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

July 20, 2015

JJGC Industria e Comercio de Materiais Dentarios SA
c/o Mr. Kevin Thomas
PaxMed International, LLC
12264 El Camino Real, Ste 400
San Diego, California 92130

Re: K141777
Trade/Device Name: Neodent Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: June 15, 2015
Received: June 16, 2015

Dear Mr.Thomas,

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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 Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141777

Device Name

Neodent Implant System

Indications for Use *(Describe)*

Zygomatic Implants are indicated for surgical installation in the zygoma region, in cases of severe jaw resorption, in order to restore patient esthetics and chewing function. Zygomatic Implants are recommended for the posterior (pre-molar/ molar) region, one implant on each side, with at least two standard dental implants in the anterior region to support a fixed restoration. Zygomatic Implants may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
JJGC Indústria e Comércio de Materiais Dentários SA
Neodent Implant System
K141777

July 1, 2015

Manufacturer Name	JJGC Indústria e Comércio de Materiais Dentários SA Av. Juscelino Kubitschek de Oliveira, 3291 - CIC Curitiba, Paraná, 81270-200, Brazil Telephone: +55 41 2169 1003 Fax: +55 41 2169 1043
Official Contact	Jacson Cambruzzi Head of Quality and Regulatory Affairs
Representative/Consultant	Kevin A. Thomas, PhD Floyd G. Larson PaxMed International, LLC 12264 El Camino Real, Suite 400 San Diego, CA 92130 Telephone +1 (858) 792-1235 Fax +1 (858) 792-1236 Email kthomas@paxmed.com flarson@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	Neodent Implant System
Common Name	Endosseous dental implant Endosseous dental implant abutment
Classification Regulations	21 CFR 872.3640
Product Code	DZE NHA
Classification Panel	Dental Products Panel
Reviewing Branch	Dental Devices Branch

INTENDED USE

Zygomatic Implants are indicated for surgical installation in the zygoma region, in cases of severe jaw resorption, in order to restore patient esthetics and chewing function. Zygomatic Implants are recommended for the posterior (pre-molar/molar) region, one implant on each side, with at least two standard dental implants in the anterior region to support a fixed restoration. Zygomatic Implants may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.

DEVICE DESCRIPTION

This submission includes threaded root-form dental implants designed for placement into the zygomatic bone with either an external hexagon abutment interface, or a Morse taper abutment interface. Both implant designs are provided with a thread major diameter of 4.4 mm at the coronal end of the implant (over a length of 10 mm), which tapers to a thread major diameter of 3.9 mm for the remaining implant length. Both implant designs are provided in multiple threaded lengths ranging from 30 mm to 52.5 mm. All implants are made of commercially pure titanium, Grade 4, conforming to ASTM F67, *Standard Specification for Unalloyed Titanium for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700).*

This submission includes transepithelial abutments with external hexagon or Morse taper interfaces for connection to the zygomatic implants. The external hexagon abutments have a platform diameter of 4.1 mm and are provided in gingival heights of 3, 4, or 5 mm. The Morse taper transepithelial abutments also have a platform diameter of 4.1 mm and are provided in gingival heights of 1.5, 2, 3, 4, or 5 mm.

This submission also includes a Protection Cylinder that is used to protect the abutment during healing of the gingival tissue. The Protection Cylinder may be installed on either abutment design (external hexagon or Morse taper) with the corresponding Protection Cylinder Screw.

All transepithelial abutments, external hexagon transepithelial abutment screws, protection cylinders, and protection cylinder screws are made of titanium alloy conforming to ASTM F136 *Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401).*

All zygomatic implants are packaged assembled with the corresponding implant mount and provided sterilized by gamma irradiation. All transepithelial abutments, external hexagon transepithelial abutment screws, protection cylinders, and protection cylinder screws are provided sterilized by exposure to ethylene oxide.

PERFORMANCE DATA

Non-clinical data submitted, referenced, or relied upon to demonstrate substantial equivalence include: biocompatibility, engineering analysis, dimensional analysis, and dynamic compression-bending testing according to ISO 14801 *Dentistry – Implants – Dynamic fatigue test for endosseous dental implants.*

Clinical literature data were submitted in this premarket notification including reports of 45 subjects treated with a total of 90 predicate device (K070182) zygomatic implants in combination with 165 conventional dental implants, and 16 subjects treated with a total of 37 subject device zygomatic implants in combination with 58 conventional dental implants. All subjects were treated for rehabilitation of maxillary atrophy for restoration of aesthetics and chewing function. The subjects who received the predicate zygomatic implants were treated by a

delayed loading protocol in 44 of 45 cases (1 case of immediate loading); all subjects who received the subject device zygomatic implants had immediate loading (within 48 hours of surgical placement). Follow-up time periods for all subjects ranged from 6 to 36 months. For the subjects who received the predicate zygomatic implants, survival of the zygomatic implants was 100% and survival of the conventional implants ranged from 85.7 to 100%. Subjects who received the subject device zygomatic implants had 100% survival of all implants (zygomatic and conventional) after immediate loading at 12 months. These clinical data demonstrate the subject device is as safe, as effective and performs as well as the predicate device in the atrophic maxilla.

EQUIVALENCE TO MARKETED DEVICES

Neodent Implant System is substantially equivalent in indications and design principles to the following legally marketed predicate devices:

Nobel Biocare USA, LLC, Zygoma Implant, K070182;

JJGC Indústria e Comércio de Materiais Dentários SA, Neodent Implant System, K133510; and

JJGC Indústria e Comércio de Materiais Dentários SA, Neodent Implant System, K123022.

The primary predicate device is K070182. The reference predicate devices are K133510 and K123022. A comparison of the technological characteristics of the subject device and the primary predicate device K070182 is provided in the following table.

	Subject Device	**Primary Predicate Device**
Comparison	JJGC Indústria e Comércio de Materiais Dentários SA Neodent Implant System K141777	Nobel Biocare USA, LLC Zygoma Implant K070182
Indications for Use	Zygomatic Implants are indicated for surgical installation in the zygoma region, in cases of severe jaw resorption, in order to restore patient esthetics and chewing function. Zygomatic Implants are recommended for the posterior (pre-molar/molar) region, one implant on each side, with at least two standard dental implants in the anterior region to support a fixed restoration. Zygomatic Implants may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.	Nobel Biocare's Zygoma implants are endosseous dental implants intended to be surgically placed in the bone of the upper jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore patient esthetics and chewing function. The Zygoma Implants may be put into immediate function provided that stability requirements detailed in the manual are satisfied.
Implants		
Design	Threaded root-form implant to be used with mating abutments	External hex threaded root-form implant to be used with mating abutments
Platform (Ø)	4.1 mm	4.1 mm
Thread (major Ø)	4.4 mm tapering to 3.9 mm	4.4 mm tapering to 3.9 mm
Length, mm	External hex: 30, 35, 40, 45, 47.5, 50, 52.5	30, 35, 40, 45, 47.5, 50, 52.5
	Morse taper: 30, 35, 40, 42.5, 45, 47.5, 50, 52.5	n/a
Implant-Abutment Interface		
Type	External hex and Morse taper	External hex
Implant Head Angle	45°	45°
Implant Surface	Machined	Machined

	Subject Device	Primary Predicate Device
Comparison	JJGC Indústria e Comércio de Materiais Dentários SA Neodent Implant System K141777	Nobel Biocare USA, LLC Zygoma Implant K070182
Abutments		
Platform (Ø)	4.1 mm	4.1 mm
Abutment Angle	0° (straight)	0° and 17°
Gingival Height	External hex: 3, 4, 5 mm	External hex: 2, 3, 5 mm
	Morse taper: 1.5, 2, 3, 4, 5 mm	n/a
Materials		
Implants	F67 commercially pure titanium, grade 4	Commercially pure titanium
Implant Mount	F136 Ti-6Al-4V ELI	Not stated
Implant Mount Screw	F136 Ti-6Al-4V ELI	Not stated
Abutments	F136 Ti-6Al-4V ELI	F136 Ti-6Al-4V ELI
Abutment Screws	External hex: F136 Ti-6Al-4V ELI	Not stated
Protection Cylinders	F136 Ti-6Al-4V ELI	n/a
Protection Cylinder Screws	F136 Ti-6Al-4V ELI	n/a

The subject device and the primary predicate K070182 have substantially equivalent indications for use, including restoration of patient esthetics and chewing function, and immediate loading when used with standard dental implants placed in the anterior region to support a fixed restoration. The implants of the subject device and the predicate device K070182 have similar designs, dimensions, materials, and machined surface finish. The abutments of the subject device have similar designs, similar dimensions, and are made from similar or identical materials as those cleared under K070182, K133510, and K123022. The subject device includes both external hexagon and Morse taper abutment-implant interface connections, whereas the K070182 predicate device includes only external hexagon connections. The subject device includes only straight abutments, whereas the K070182 predicate device abutments are provided in both straight and 17° angled designs. The subject device external hexagon abutments are provided in gingival heights of 3, 4, and 5 mm, whereas the K070182 predicate device external hexagon abutments are provided in gingival heights of 2, 3, and 5 mm.

The subject device has similar packaging and is sterilized using the same materials and processes as the predicate devices in K133510, and K123022.

CONCLUSION

The subject device and the predicate devices have the same intended use, have similar technological characteristics, and are made of similar materials. The subject device and predicate devices encompass the same range of physical dimensions, including diameter and length of the implants, and diameter, gingival height, and angle of the abutments. The subject and predicate devices are packaged in similar materials and sterilized using similar methods.

The data included in this submission demonstrate substantial equivalence to the predicate devices listed above.

Predicate Device Literature

Blue Sky Bio, LLC

Blue Sky Bio Dental Implant System

K102034

Device Classification Name	Implant, Endosseous, Root-Form[23]
510(K) Number	K102034
Device Name	BLUE SKY BIO DENTAL IMPLANT SYSTEM
Applicant	BLUE SKY BIO, LLC 888 E Belvidere Rd. Suite 212 Grayslake, IL 60030
Applicant Contact	Albert Zickmann
Correspondent	BLUE SKY BIO, LLC 888 E Belvidere Rd. Suite 212 Grayslake, IL 60030
Correspodent Contact	Albert Zickmann
Regulation Number	872.3640[24]
Classification Product Code	DZE[25]
Subsequent Product Code	NHA[26]
Date Received	07/19/2010
Decision Date	04/19/2011
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	Dental
510k Review Panel	Dental
Summary	Summary[27]
Type	Traditional
Reviewed By Third Party	No
Combination Product	No

Blue Sky Bio, LLC

888 E BELVIDERE
SUITE 212
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

Blue Sky Bio, LLC

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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

Blue Sky Bio, LLC

888 E BELVIDERE
SUITE 212
GRAYSLAKE, IL 60030
Tel: 718-376 0422
Fax: 888-234 3685

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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Attachment 2

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

Blue Sky Bio, LLC

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SUITE 212
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Tel: 718-376 0422
Fax: 888-234 3685

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.

Blue Sky Bio, LLC

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GRAYSLAKE, IL 60030
Tel: 718-376 0422
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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:

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.

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

Predicate Device Literature

Blue Sky Bio, LLC

Blue Sky Bio Dental Implant System

K060957

Device Classification Name	Implant, Endosseous, Root-Form[23]
510(K) Number	K060957
Device Name	MODIFICATION TO BLUE SKY BIO DENTAL IMPLANT SYSTEM
Applicant	BLUE SKY BIO, LLC 888 E Belvidere Rd. Suite 212 Grayslake, IL 60030
Applicant Contact	Michelle Vovolka
Correspondent	BLUE SKY BIO, LLC 888 E Belvidere Rd. Suite 212 Grayslake, IL 60030
Correspodent Contact	Michelle Vovolka
Regulation Number	872.3640[24]
Classification Product Code	DZE[25]
Date Received	04/07/2006
Decision Date	05/05/2006
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	Dental
510k Review Panel	Dental
Summary	Summary[26]
Type	Special
Reviewed By Third Party	No
Combination Product	No

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

Blue Sky Bio, LLC

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Email: azickmann@blueskybio.com

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)

Sung-Kwon

...sthesiology, General Hospital,
...Control, Dental Devices

...K060957

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

Predicate Device Literature

Southern Implants, Inc.

Zygomatic Implant System

K093562

Device Classification Name	Implant, Endosseous, Root-Form[23]
510(K) Number	K093562
Device Name	ENDOSSEOUS DENTAL IMPLANT
Applicant	SOUTHERN IMPLANTS, INC. 5 Holland Bldg 209 Irvine, CA 92618
Applicant Contact	Michael Kehoe
Correspondent	SOUTHERN IMPLANTS, INC. 5 Holland Bldg 209 Irvine, CA 92618
Correspodent Contact	Michael Kehoe
Regulation Number	872.3640[24]
Classification Product Code	DZE[25]
Date Received	11/18/2009
Decision Date	10/14/2010
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	Dental
510k Review Panel	Dental
Summary	Summary[26]
Type	Traditional
Reviewed By Third Party	No
Combination Product	No

K093502

510(K) PREMARKET NOTIFICATION SUMMARY

Name/Address of Submitter: Southern Implants, Inc.
5 Holland, Bldg. 209
Irvine, CA 92618

OCT 14 2010

Establishment Registration Number: 3003845138

Contact Person: Michael A. Kehoe
Phone: (866) 700-2100 x 225
Fax: (949) 273-8508

Date Summary Prepared: October 20, 2009

Device Classification Name: Endosseous Implant and Accessories

Device Classification Regulation Number: 21 CFR 872.3640

Device Regulatory Status: Class II Special Controls

Trade Name: Zygomatic Implant

Purpose: The purpose of this 510(k) is to include additional implants and accessories in the Southern Implant System that did not fall within the size range and design shapes identified in prior 510(k) submissions.

Performance Standards: FDA has not established a performance standard applicable to endosseous implants and their accessories. The materials in Southern's Zygomatic Implant System meet applicable voluntary standards. Southern Implant's screw-type implants and abutments are manufactured from ASTM F67-95 Grade III or Grade IV Titanium.

Predicate Devices: K970499 Branemark System Zygomatic Implant; K070182 Nobel Biocare Zygoma Implant

Device Description and Intended Use: The Zygomatic implant is intended to be implanted in the upper jaw arch to provide support for fixed or removable dental prostheses in patients with fully or partially edentulous maxillae.

Sterilization Methods Used: Sterilization of these implants will be achieved using Co60 irradiation, with a minimum dose of 25.0 kGy (2.5 m rads), creating a Sterility Assurance Level of 10^{-6}. Validation of sterilization will be done as specified by the Association for the Advancement of Medical Instrumentation (AAMI). Standards utilized include:

ISO 11137	Sterilization of Health Care Products – Requirements for validation and routine control – Radiation sterilization
ISO 11137-2	Sterilization of Medical Devices – Microbial Methods – Part 2: Tests of sterility performed in the validation of a sterilization process
ISO 13409	Sterilization of Health Care Products – Radiation Sterilization – substantiation of 25kGy as a sterilization dose for small or infrequent production batches.

Packaging Method: Please note that our implants are packaged the same as our existing line of dental implants that are cleared NSI hexed and non-hexed Implant Systems noted above as predicate devices. Implants are placed into plastic tubing (PT6.1) and capped on both ends. The plastic tube is then heat sealed in a blister pack consisting of a transparent film (P.E.T.) and a porous sheet material backing (Tyvek1073B). This blister pack is considered the primary pack (that which provides the microbial barrier) for the implants. The Tyvek is coated with an adhesive. A sterilization indicator sticker is placed on the blister packaging. The blister with its contents are then enclosed in a clear plastic box and sent for sterilization.

Packaging Validation: All Southern Implants packaging is validated following these standards:

ASTM D 4169-08	Standard Practice for Performance Testing of Shipping Containers and Systems
ASTM F 88-00	Standard Test Method for Seal strength of Flexible Barrier Materials
ASTM F 1929-98	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
ASTM F 1980 – 07	Standard Guide for Accelerated Aging of Sterile Medical Device Packages
EN 552	Sterilization of medical devise – Validation and routine control of sterilization by irradiation
EN556	Sterilization of medical devices – Requirements for medical devices to be labeled "Sterile"
EN 868-1:1997	Packaging materials and systems for medical devices with are to be sterilized: Part 1 General requirements and test methods
EN 868-5:1999	Packaging materials and systems for medical devices which are to be sterilized – Part 5: Heat and self-sealable pouches and reels of paper and plastic film construction – Requirements and test methods
EN 868-9: 2000	Packaging materials and systems for medical devices which are to be sterilized – Part 9: Uncoated non-woven materials of polyolefines suitable for use as packaging of medical devices which are to be terminally sterilized – Requirements and test methods.
EN 868-10:2000	Packaging materials and systems for medical devices which are to be sterilized – Part 10: Adhesive coated nonwoven material of polyolefines for use in the manufacture of heat sealable pouches, reels and lids – Requirement s and test methods
ISO 11607	Packaging for terminally sterilized medical devices

Technological Characteristics: The physical properties and designs of the additional implants and accessories in the NSI Endosseous Dental Implant System were compared with legally marketed predicate devices. The technological characteristics were comparable.

Surface Modifications: Please note that this is the same surface modification method currently used with our existing line of dental implants that are cleared NSI hexed and non-hexed Implant Systems noted above as predicate devices. The surface of our implant is blasted using 100 micron alumina (Al_2O_3) particles. Alumina is a highly biocompatible material and hence if any particles remain embedded in the surface, they will not pose a complication. The other measure taken to reduce the potential of embeddiment is to blast with relatively low pressure. If the indentations caused are significantly smaller than the size of the blast media, then particles tend to not adhere to the surface. (Our S_a = 1.43 microns is a fraction of the particle size of 110 microns). Each and every implant is visually inspected under a microscope after surface enhancement as a matter of manufacturing protocol. In addition to visual inspection, a sample implant is sent for SEM testing four times a year for evaluation of the surface as well.

Brief Discussion of Clinical Studies: Clinical studies were not conducted, or deemed necessary, for the purpose of this 510(k) submission.

Brief Discussion of Engineering Studies: Fatigue studies were conducted as per FDA Class II Special Controls Guidance Document and ISO standard 14801: 2007(E). Testing revealed a stable screw joint at the highest forces tested. See enclosed study.

Conclusions Drawn: The Southern Zygomatic Implant System has the same intended use as, and technological characteristics similar to, the legally marketed predicate devices. Any differences in the technological characteristics did not raise new issues of safety or effectiveness.

ENCLOSURE 1

Comparison of Properties and Features of Southern's 4.0 mm 55° angle-corrected implant to Nobel Biocare's Zygomatic 45° implant

	Southern 55°angle corrected tapered implant	Nobel Biocare Zygomatic 45° Implant
Specification for material	ASTM Grade IV titanium	Titanium
Exterior geometry	Threaded	Threaded
Implant width at restorative platform (mm)	4.05	4.0
Implant lengths (mm)	35, 37.5, 40, 42.5, 45, 47.5, 50, 52.5, 55	30, 35, 40, 42.5, 45, 47.5, 50, 52.5
Maximum diameter (mm)	4.05	4.1
Apical end diameter (mm)	3.8	2.8
Hex width x height (mm)	2.7 x 0.7	2.7 x 0.7
Internal screw access width (mm)	2.0	2.0
Angle of screw access opening relative to long axis of implant	55°	45°

Indication for Use: The Zygomatic implant is intended to be implanted in the upper jaw arch to provide support for fixed or removable dental prostheses in patients with fully or partially with fully or partially edentulous maxillae.

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

Mr. Michael A. Kehoe
President and Chief Executive Officer
Southern Implants, Incorporated
5 Holland Building 209
Irvine, California 92618

OCT 14 2010

Re: K093562
Trade/Device Name: Zygomatic Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: September 23, 2010
Received: September 24, 2010

Dear Mr. Kehoe:

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

Indication for Use

OCT 1 4 2010

510(k) Number: K093562

Device Name: Zygomatic Implant System

Indication for Use: The Zygomatic implant is intended to be implanted in the upper jaw arch to provide support for fixed or removable dental prostheses in patients with partially or fully edentulous maxillae.

Concurrence of CDRH Office of Device Evaluation

Prescription Use ✓ OR Over-the-counter Use _____.
(Per 21 CFR801.109)

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

510(k) Number: K093562

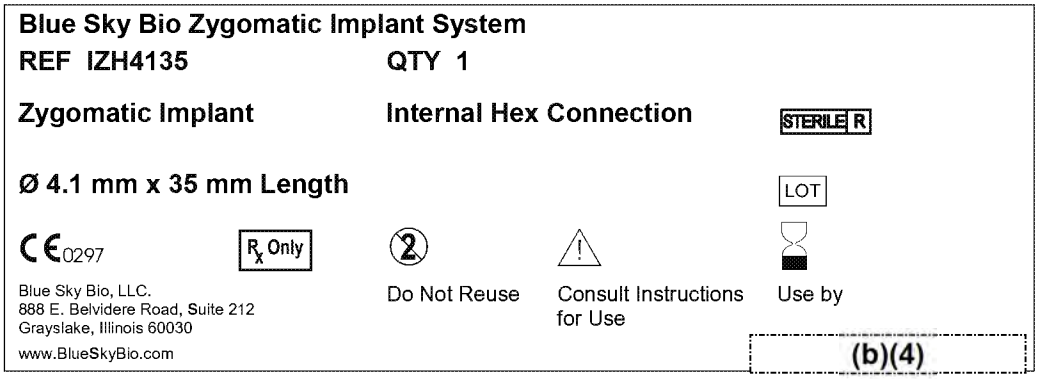
13. Proposed Labeling

Proposed Labeling

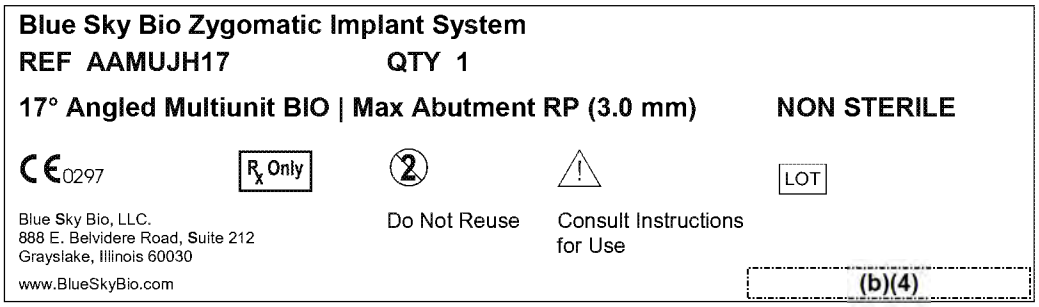
This proposed labeling section includes representative copies of a draft product label and the draft Instructions for Use.

The subject device qualifies for Exemptions from Adequate Directions for Use (21 CFR 801, Subpart D) because it is a prescription device.

Draft Product Labels



Draft sterile device product label



Draft nonsterile device product label

Draft Instructions for Use

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(b)(4)

(b)(4)

(b)(4)

14. Sterilization and Packaging

Sterilization and Packaging

Sterilization

All subject device zygomatic implants are provided sterile by means of Co^{60} gamma irradiation. Sterilization has been validated to a sterility assurance level (SAL) of 10^{-6} by selecting and substantiating a 25 kGy dose using method VD_{max}^{25}, according to ISO 11137-1 *Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices* and ISO 11137-2 *Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose.*

The subject device abutments (and the corresponding previously cleared abutment screws) are provided nonsterile and are to be sterilized by the end user. (b)(4)

(b)(4)

(b)(4) according to ISO 17665-1 *Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices,* and ISO 17665-2 *Sterilization of health care products – Moist heat – Part 2: Guidance on the application of ISO 17665-1.*

The subject device is not represented to be "pyrogen free."

Packaging

(b)(4)

All subject device abutments (and the corresponding previously cleared abutment screws) are packaged in single units sealed in an autoclavable pouch. The subject device abutments (and the corresponding previously cleared abutment screws) are provided nonsterile and are to be sterilized by the end user using the moist heat autoclave cycle described above.

Shelf Life

The sterile barrier shelf life for the subject device is (b)(4). The packaging for the subject device is the same as for other Blue Sky Bio sterile dental implant products and, therefore, prior shelf life validations are applicable to the subject device.

The real-time shelf life was determined by testing samples after aging for (b)(4) Package integrity of the sterile barrier was evaluated by seal strength testing according to ASTM F88 *Standard Test Method for Seal Strength of Flexible Barrier Materials*, and by dye immersion testing.

The subject device implants and abutments are not adversely affected by aging because the subject device is made from Ti-6Al-4V, known to be stable in air at room temperature for an indefinite period of time.

15. Biocompatibility

Biocompatibility

The subject device is a permanent, tissue/bone implant device intended for more than (b)(4) of patient contact.

The subject device implants and abutments are made of titanium alloy conforming to ASTM F136, *Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)*. This titanium alloy is commonly used in endosseous dental implants and abutments, and is the same material used for the Blue Sky Bio components previously cleared in K102034 and K060957. The subject device zygomatic implants are provided with the same grit-blasted and acid etched surface as used on the implants cleared in K102034 and K060957.

FDA Blue Book Memorandum #G95-1 *Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing"* states that "Some devices are made of materials that…have a long history of safe use. For the purposes of demonstrating the substantial equivalence of such devices to other marketed products, it may not be necessary to conduct all the tests suggested in the FDA matrix of this guidance."

As recommended in FDA recognition (2-179) of ISO 10993-1 *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process,* the titanium alloy and the final finished subject devices identified in this submission are identical in "formulation, processing, component interactions, and storage conditions" to the predicate devices in K102034 and K060957.

All of the subject device components are manufactured in the same facilities using the same manufacturing processes as used for the Blue Sky Bio components previously cleared in K102034 and K060957. Therefore, no new biocompatibility testing has been performed, as the subject device is substantially equivalent to the predicate devices in K102034 and K060957 with regards to materials and processing.

16. Software

(Not applicable – the subject device does not contain software)

17. Electromagnetic Compatibility and Electrical Safety

(Not applicable – the subject device does not require EMC and electrical safety evaluation)

18. Performance Testing – Bench

Performance Testing – Bench

Mechanical testing was performed to ensure that the strength of the Blue Sky Bio Zygomatic Implant System is appropriate for its intended use. (b)(4)

(b)(4)

(b)(4)

Engineering Drawings of Test Components

(b)(4)

(b)(4)

Mechanical Testing Report

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19. Performance Testing – Animal

(Not applicable – submission does not include animal testing data)

20. Performance Testing – Clinical

(Not applicable – submission does not include clinical data)

21. Other

(Not applicable)

PAXMED INTERNATIONAL

Consulting Services in Medical Devices

Regulatory Affairs
Biomaterials
Clinical Trials
Initial Importer
Quality Systems

March 31, 2016

Andrew I. Steen
U.S. Food and Drug Administration
Center for Devices and Radiological Heath
Document Control Center – W066-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: Additional Information – K153064, Blue Sky Bio Zygomatic Implant System

Dear Mr. Steen:

Thank you for your review of the above referenced Premarket Notification. On behalf of Blue Sky Bio, LLC, we hereby submit this response request for additional information regarding the subject submission as conveyed in your email of January 5, 2016.

This response is submitted as one paper copy and one eCopy on a CD. The eCopy is an exact duplicate of the paper copy.

FDA Deficiency

(b)(4)

PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130 USA
Tel 1 858 792-1235 • Fax 1 858 792-1236 • www.paxmed.com

(b)(4)

(b)(4)

(b)(4)

Thank you for your review of this submission. If you need additional information, please contact me or Floyd Larson at your earliest convenience.

Sincerely,

(b)(6)

Kevin A. Thomas, PhD
Vice President, Director of Regulatory Affairs

cc: Blue Sky Bio, LLC

Attachments

1. Revised 510(k) Summary – Clean and Redline Copies
2. Revised Instructions for Use – Clean and Redline Copies
3. Revised Subject Device Product List and a revised table of Subject Device Implant-Abutment Compatibilities
4. (b)(4)

Attachment 1

Revised 510(k) Summary

Clean and Redline Copies

510(k) Summary

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510(k) Summary

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Attachment 2

Revised Instructions for Use

Clean and Redline Copies

Blue Sky Bio Zygomatic Implant System
Revised – Instructions for Use

Indications

Blue Sky Bio Zygomatic Implant System is indicated for surgical installation in the zygoma region, in cases of severe jaw resorption, in order to restore patient esthetics and chewing function. Blue Sky Bio zygomatic implants are recommended for the posterior (pre-molar/molar) region, one implant on each side, with at least two standard dental implants in the anterior region to support a fixed restoration. Blue Sky Bio zygomatic implants may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.

Contraindications

Implants should not be placed anytime when there are general contraindications associated with elective oral surgery.

Absolute and relative contraindications include, but are not limited to: cardiac and vascular disease, bleeding disorders, psychological disorders, uncontrolled diabetes mellitus, mineral, bone, or connective tissue disorders, renal disease, hepatic disease, auto-immune disorders, decreased immune function due to disease or medications, infectious disorders, and adverse conditions caused by medications. Further relative contraindications include poor oral hygiene, bruxism, malnutrition, alcoholism, tobacco usage, and history of radiation therapy.

In addition, the patient needs an adequate volume of residual bone for the placement of implants of sufficient size and number to support the anticipated functional loads to which the patient will subject these implants.

Warning

Implants should be placed and restored only by practitioners who are licensed and trained to perform these procedures. Adequate preoperative studies should be performed to examine the anatomic structures and to assess the biomechanical, functional, and esthetic requirements of each case. Radiographs or other diagnostic reviews should be performed to determine position and topography of the maxillary sinus, nasal cavities, natural tooth positions and other anatomical features that may affect implant placement or prognosis. Consultation between the surgeon, restorative dentist, and dental laboratory is essential for success.

Risks of implant placement and restoration include, but are not limited to: infection, implant failure, loss of bone and soft tissue, unfavorable aesthetic result, anesthesia, dysesthesia and paresthesia in the oral and facial areas, sinus infection, dislodgement of implants and instruments in the surrounding structures, non-restorable implants, fracture of implants or restorative components, and loosening of implants or restorative components.

Each implant system has unique measuring characteristics to allow full seating of the implant to the desired depth. In some instances, drill length reference lines measure longer than the stated length of the implant. It is recommended that the implant surgeon be thoroughly familiar with the specific measurement system being utilized and provide a suitable safety margin adjacent to any teeth and vital structures. Failure to recognize the difference between the actual length of the drill and radiographic

measurements can result in permanent injury to the nerves or other vital structures by drilling beyond the depth intended, potentially resulting in permanent numbness other injuries.

Each implant system has specific design characteristics for mating implants, abutments, prosthetic components, and instrumentation. Combining instruments and components that are not configured or dimensioned for correct mating can lead to mechanical failure of components, damage to tissue, or unsatisfactory aesthetic results.

One-hundred percent success cannot be guaranteed. Lack of adequate quantity and/or quality of remaining bone, infection, inadequate surgical technique, poor patient oral hygiene, and generalized disease are some potential causes for failure of osseointegration, both immediately after surgery or after osseointegration is initially achieved. Pre-operative hard tissue or soft tissue deficits may yield a compromised aesthetic result or unfavorable implant angulation. With respect to children, routine treatment is not recommended until completion of alveolar growth has been verified.

Precaution - MRI Safety Information

The Blue Sky Bio Zygomatic Implant System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Blue Sky Bio Zygomatic Implant System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Procedural Precautions, Surgery

All efforts must be made to minimize damage to the host tissue. In particular, special attention must be paid to thermal and surgical trauma and to the elimination of contaminants and sources of infection. The surgical procedure requires a high degree of precision and care. Any divergence from the principle of least possible trauma at implant installation increases the risk of failure to establish osseointegration. The use of sharp drills, sufficient irrigation, an in-and-out drilling motion, short cutting cycles, waiting for the bone to cool, and use of pilot drills in successively increasing sizes are essential. Special care should be taken to avoid over or under preparation of the osteotomy. Implants should be inserted in such a way that they are stable and lack any mobility. Excessive insertion torque (greater than 60 Ncm) may lead to damage to the implant or instruments and fracture or necrosis of the bone site. All instruments used in surgery must be maintained in good condition and care must be taken that the instruments do not damage the implants or other components. Precautions must be taken to avoid the swallowing or aspiration of components used in implant dentistry. After the implant installation, the surgeon's evaluation of bone quality and initial stability will determine when implants may be loaded. An appropriate follow-up protocol should be followed.

Specific Surgical instructions

A crestal incision is made from just anterior to the maxillary tuberosity on one side to the same point on the other side. Vertical releasing incisions are made in the second molar regions and the midline. These incisions facilitate flap mobilization to visualize the posterior maxilla and zygomatic buttress.

Mucoperiosteal flaps are raised to expose the infraorbital nerve, the body of the zygoma and the zygomatic arch. A palatal flap is raised to expose the alveolar bone. The periosteum in the region of the upper molar teeth is incised to enhance flap mobility.

A window is cut on the lateral aspect of the maxillary antrum and the bone covering the window is removed. The lining of the sinus is reflected, attempting to keep it intact if possible. NB: A perforation of the lining is not desired but does not constitute a major complication. Reflection of the lining is essential in the area in which the implant will be placed to avoid interposition of soft tissue between the implant and the surrounding bone.

The access cavity of the implant into the body of the zygoma is made through the antral window, and the tip of the placement device is positioned in the access cavity. This acts as a guide for the correct alignment of the implant on the alveolar ridge.

An alternative approach is to plan the implant placement through the alveolus and lateral to the maxilla with the apical part of the implant in the zygomatic buttress. This approach does not require exposure of the maxillary sinus.

The lip should be protected via the use of labial guard tube around the drills near the head of the handpiece.

Drill Sequence

-Round Bur Starter Drill
-Twist Drill 2.7mm
- Twist Drill 3.8 mm (Final Drill for 4.3mm implants)
- Twist Drill 4.2mm (Final Drill for 4.7mm implants)
-Twist Drill 4.6mm (Final Drill for 5.0 mm Implants)

The drilling should be performed at 1000 RPM and with copious irrigation to prevent overheating of the bone. The depth of the prepared implant site and the implant angulation are verified with an angled depth gage. The markings on the twist drills correspond to the lengths of the implants to be placed. After each osteotomy the probes should be used to explore the osteotomy to make sure of the condition of the bone and extent of the osteotomy. Care should be taken to not extend beyond the apical end of the zygomatic process or at most extending 1/2 mm beyond for bicortical stabilization.

The osteotomy should be irrigated with sterile saline and should be free of any debris or soft tissue. Initial insertion of the implant is carried out using a handpiece implant driver with the torque control set at 50 Ncm at 15 – 25 RPM. If the implant is not fully seated at maximum torque, the insertion is completed using a ratchet and with an implant ratchet driver. The ideal position of the hexagon is with a flat side towards the angulation corrected with an angled abutment.

In order to have adequate force distribution a total at least 4 (combination of zygomatic and traditional) implants must be placed.

Restorative Procedure

Zygomatic implants are usually loaded immediately with a temporary restoration and they are intended to be used in combination with traditional implants placed in the anterior area of the maxilla. In order to make the restorative process easier it is recommended to use zygomatic and traditional implants with cross compatible components. In order to have a good load distribution on all implants a rigid temporary restoration should be secured passively on all implants. This temporary restoration should be replaced with a final restoration utilizing a rigid bar resting passively on all abutments. The prosthetic

components should correct the angulation of the implants in such a way that the bar has a path of draw and this can be achieved by selecting a combination of straight and angled abutments. The recommended insertion torque of the abutment screws is 30Ncm and the insertion torque of the screws connecting the bar to the multiunit abutments is 20 Ncm.

Follow Up Care

Patients should be instructed in appropriate oral hygiene and care of the implants and restorations. Periodic follow up appointments should be made to confirm and maintain adequate function of the implants and the health of the surrounding tissues.

Sterility

All implants are supplied sterile, and are for single use only prior to the labeled expiration date (if applicable). Do not use implants if the packaging has been damaged or previously opened. Abutments and instruments are supplied non-sterile and must be cleaned and sterilized prior to use.

The recommended method is moist heat (steam) sterilization cycle is:
gravity-displacement, wrapped, 30 minute exposure at 121 °C (250 °F), and 15 minutes of drying.
Use a wrap that is FDA cleared for the indicated cycle.

Method of Supply

Blue Sky Bio implants and abutments are made out of medical grade titanium alloy (Ti-6Al-4V).

Caution

The sale of this device is restricted to, or by the order of, licensed physicians or dentists.

Manufactured by:

Blue Sky Bio, LLC
888 East Belvidere Road Suite
Grayslake, IL 60030
U.S.A.

BSBZ IFU 99-9999 Rev00
2016-03

(b)(4)

(b)(4) Instructions for Use

(b)(4)

(b)(4)

(b)(4)

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Attachment 3

Revised Subject Device Product List

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Attachment 4

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Mechanical Test Report

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From: Massey, Cherryace * [Cherryace.Massey@fda.hhs.gov]
Sent: 10/22/2015 6:45:11 PM
To: kthomas@paxmed.com
CC: DCCLetters [DCCLetters@fda.hhs.gov]
Subject: K153064 ACK LETTER
Attachments: Acknowledgment%20Letter.pdf

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
CDRH/ODE/DAGRID/DEDB
WO66 RMG312
10903 New Hampshire Ave
301-796-6284

Premarket Notification [510(k)] Review

Date: April 27, 2016

Reviewer: Andrew I. Steen, Mechanical Engineer

Subject: Traditional 510(k)# K153064/S002

Applicant: Blue Sky Bio, LLC	**Device Trade Name:** Blue Sky Bio Zygomatic Implant System
Contact Name: Kevin Thomas	**Contact Title:** Regulatory Affairs
Correspondent Firm: Paxmed International, LLC	**Phone:** 1 (858) 792-1235 **Email:** kthomas@paxmed.com
Received Date: March 31, 2016	**Due Date:** April 30, 2016
Reg #: 872.3640 **Reg Name:** Endosseous Dental Implant	**Class:** II **Product Code(s):** DZE
Reg #: 872.3630 Reg Name: Endosseous dental implant abutment	Class: II Product Code(s): NHA

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Owner
K141777	DZE, NHA	Neodent Implant System	Jjgc Industria E Comercio De Materiais Dentarios S
K102034	DZE, NHA	Blue Sky Bio Dental Implant System	Blue Sky Bio, LLC
K060957	DZE	Modification To Blue Sky Bio Dental Implant System	Blue Sky Bio, LLC
K093562	DZE	Endosseous Dental Implant	Southern Implants, Inc.

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November 4, 2015</br></br>

Acceptance Review Notification - Refuse To Accept (RTA)

We have completed the administrative acceptance review of your premarket notification (510(k)) submission K153064. Our review indicates that your 510(k) submission does not meet the criteria established for administrative completeness. Thus, we regret to inform you that we are unable to conduct a substantive review of your submission at this time and are placing it on RTA hold.

Please submit two copies of your response (1 eCopy and 1 paper copy), referencing the 510(k) number K153064, addressing the elements identified as missing or inconsistent in the attached checklist to:

U.S. Food and Drug Administration

Center for Devices and Radiological Heath

Document Control Center - WO66-G609

10903 New Hampshire Avenue

Silver Spring, MD 20993-0002

FDA will permit your 510(k) submission to remain on hold for a maximum of 180 days from the date of this email. If you do not correct the missing or inconsistent elements identified in the checklist within 180 days, we will consider this 510(k) submission to be withdrawn, and we will delete it from our review system.

Upon receipt of the requested information, FDA will conduct another administrative review of your 510(k) submission.

Should you have questions about this email, you may contact Andrew Steen, the lead reviewer assigned to your 510(k) submission.

For additional information regarding the Refuse to Accept Policy for 510(k)s please refer to the guidance document available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf.

 *** This is a system-generated email notification ***

April 29, 2016</br></br> We have completed our review. Please refer to the attached letter for details.

If you have any questions, please contact the lead reviewer assigned to your submission, Andrew Steen.

 *** This is a system-generated email notification ***

Contains Nonbinding Recommendations

Print Form

Acceptance Checklist for Traditional 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.
FDA recommends that the submitter include this completed checklist as part of the submission.

510(k) #: K153064 Date Received by DCC: Oct 22, 2015

Lead Reviewer: Andrew I. Steen Trade Name: Blue Sky Bio Zygomatic Implant System

Branch: DEDB Division: DAGRID Center/Office: CDRH/ODE

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means the reviewer did not assess the element during the RTA review and that the element will be assessed during substantive review.

IMPORTANT - Many checklist elements include additional details regarding information to address the element that can be seen by hovering over the element (Example - Element 4 in Section A of the checklist).

Preliminary Questions Answers in the shaded blocks indicate consultation with a Center advisor is needed. (Boxes checked in this section represent FDAs preliminary assessment of these questions at the time of administrative review.)	Yes	No	N/A
1) Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)? If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Product Jurisdiction Liaison to determine the appropriate action, and inform division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If the product does not appear to be a device or such a combination product, mark "No."	X		
Comments:			
2. Is the submission with the appropriate Center? If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the submission is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or CBER Product Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If submission should not be reviewed by your Center mark "No."	X		
Comments:			
3) If a Request for Designation (RFD) was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following: **a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission?** **b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission?** If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Product Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide summary of Jurisdictional Officer's/Liaison's determination.* If the answer to either question above is no, mark "No." If there was no RFD, mark "N/A."			
Comments:			

4) Is this device type eligible for a 510(k) submission? If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), you should consult with the CDRH 510(k) Program Director or appropriate CBER staff during the acceptance review. If 510(k) is not the appropriate regulatory submission, mark "No."	X		
Comments:			
5) Is there a pending PMA for the same device with the same indications for use? If yes, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.		X	
Comments:			
6) If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If yes, consult with the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action. Check on web at http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm If no clinical studies have been submitted, mark "N/A."			
Comments:			

- If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and issue the "Original Jurisdictional Product" letter.
- If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Jurisdictional Officer or CBER Office of Jurisdiction Liaison.
- If the answer to 4 is "No," the lead reviewer should consult division management and other Center resources to determine the appropriate action.
- If the answer to 5 is "Yes," then stop review of the 510(k), contact the CDRH 510(k) Staff and PMA Staff, or appropriate CBER staff.
- If the answer to 6 is "Yes," then contact CDRH/OC/DBM or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with DBM or BMB Staff, and indicate their recommendation/action.

Organizational Elements

Failure to include these items should not result in an RTA designation.

*Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	*Page #
1) Submission contains a Table of Contents	X		
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	X		
3) All pages of the submission are numbered.	X		
4) Type of 510(k) is identified (i.e., Traditional, Abbreviated, or Special).	X		
Comments:			

Elements of a Complete Submission (RTA Items)
(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

- Any "No" answer will result in a "Refuse to Accept" decision; however, FDA staff has discretion to determine whether missing items are needed to ensure that the submission is administratively complete to allow the submission to be accepted or to request missing checklist items interactively from submitters during RTA review.
- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
A. Administrative					
1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	X				
2) Submission identifies the following (FDA recommends use of the CDRH Premarket Review Submission Cover Sheet form [Form 3514]):					
a) Device trade/proprietary name	X				
b) Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	X				
3) Submission contains an Indication for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109, and FDA's guidance "Alternative to Certain Prescription Devices Labeling Requirements.") *See recommended format. (http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM360431.pdf).*	X				
4) Submission contains a 510(k) Summary or 510(k) Statement.	X				
5) Submission contains a Truthful and Accuracy Statement per 21 CFR 807.87(k) *See recommended format.* *(http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142707.htm).*	X				
6) Submission is a Class III 510(k) device.			X		
7) Submission contains clinical data			X		
8) The submission identifies prior submissions for the same device included in the current submission (e.g., submission numbers for a prior not substantially equivalent [NSE] determination, prior deleted or withdrawn 510(k), Pre-Submission, IDE, PMA, etc.). **OR** States that there were no prior submissions for the subject device.	X				
a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence from prior submissions for this device are addressed.			X		
B. Device Description					
9) The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding device description that is applicable to the subject device.					
a) The submission addresses device description recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria.			X		

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
b) The submission includes device description information that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness.	X				
10) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling).	X				
11) The submission includes descriptive information for the device, including the following:					
a) A description of the principle of operation or mechanism of action for achieving the intended effect.	X				
b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	X				
c) A list and description of each device for which clearance is requested.	X				
d) Submission contains representative engineering drawing(s), schematics, illustrations, photos and/or figures of the device. **OR** Submission includes a statement that engineering drawings, schematics, etc. are not applicable to the device (e.g., device is a reagent and figures are not pertinent to describe the device).	X				
12) Device is intended to be marketed with multiple components, accessories, and/or as part of a system.	X				
a) Submission includes a list of all components and accessories to be marketed with the subject device.	X				
b) Submission includes a description (as detailed in item 11(a), 11(b) and 11(d) above) of each component or accessory.	X				
c) A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance **AND** A statement is provided that identifies components or accessories that have not received prior 510(k) clearance.	X				
C. Substantial Equivalence Discussion					
13) Submitter has identified a predicate device(s), including the following information:					
a) Predicate device identifier provided (e.g., 510(k) number, de novo number, reclassified PMA number, regulation number if exempt or statement that the predicate is a preamendment device). For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding documenting preamendment status is available online. (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/MedicalDeviceQualityandCompliance/ucm379552.htm).*	X				

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
b) The identified predicate(s) is consistent throughout the submission (e.g., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing).	X				
14) Submission includes a comparison of the following for the predicate(s) and subject device and a discussion why any differences between the subject and predicate(s) do not impact safety and effectiveness [see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)] *See "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" guidance document for more information on comparing intended use and technological characteristics.*				X	
a) Indications for Use	X				
b) Technology, including features, materials, and principles of operation		X			
Comments:	(b)(4)				
D. Proposed Labeling (see also 21 CFR part 801 and 809 as applicable)					
15) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual).	X				
a) Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided).	X				
b) Labeling includes: - Statements of conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) (21 CFR 801.5) **AND** - Includes adequate directions for use (see 21 CFR 801.5) **OR** - Submission states that device qualifies for exemption per 21 CFR 801 Subpart D	X				
16) Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1).	X				
17) Labeling includes the prescription statement [see 21 CFR 801.109(b)(1)] or Rx Only symbol (see also Section 502(a) of the FD&C Act and FDA's guidance "Alternative to Certain Prescription Device Labeling Requirements").	X				
18) The device has a device-specific guidance document, special controls document, and/ or requirements in a device-specific regulation regarding labeling that is applicable to the subject device.				X	
a) The submission addresses labeling recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria.			X		

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
b) The submission includes labeling information that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness.		X			
Comments:	(b)(4)				
19) If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10.			X		
E. Sterilization					
If an *in vitro* diagnostic (IVD) device and sterilization is not applicable, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.					
Submission states that the device, and/or accessories, and/or components are: (one of the below must be checked)					
X Provided sterile, intended to be single-use					
X Requires processing during its use-life					
Non-sterile when used (and no processing required)					
Information regarding the sterility status of the device is not provided. (If this box is checked, please also check one of the two boxes below.)					
Sterility status not needed for this device (e.g., software-only device)					
Sterility status needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *Please refer to the guidance document titled "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" for additional information.*					
20) Assessment of the need for cleaning and subsequent disinfection or sterilization information					
a) Identification of device, and/or accessories, and/or components that are provided sterile.	X				
b) Identification of device, and/or accessories, and/or components that are end user sterilized or disinfected.	X				
c) Identification of device, and/or accessories, and/or components that are reusable.			X		
21) If the device, and/or accessory, and/or a component is provided sterile:					
a) Sterilization method is stated for each component (including dose for radiation sterilization).	X				
b) A description of method to validate the sterilization parameters is provided for each proposed sterilization method (e.g., half-cycle method and full citation of FDA-recognized standard, including date).	X				

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
c) For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant residuals remaining on the device and sterilant residual limits.			X		
d) Sterility Assurance Level (SAL) is stated.	X				
e) Submission includes description of packaging.	X				
f) For products labeled "non-pyrogenic," a description of the method used to make the determination stated (e.g., limulus amebocyte lysate [LAL]).			X		
22) If the device, and/or accessory, and/or a component is reusable or end user sterilized or disinfected:					
a) Cleaning method is provided in labeling for each device, and/or accessory, and/or component.			X		
b) Disinfection method is provided in labeling for each device, and/or accessory, and/or component.			X		
c) Sterilization method is provided in labeling for each device and/or accessory, and/or component.	X				
d) Device types in this submission are listed in Appendix E of the FDA's guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling."			X		
i) If device types in this submission are included in Appendix E of the reprocessing guidance, the submission includes protocols and test reports for validating the reprocessing instructions.			X		
23) The device has a device-specific guidance document, special controls document, and/or requirement in a device-specific regulation regarding sterility and/or reprocessing that is applicable to the subject device.	X				
a) The submission addresses sterility and/or reprocessing recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria.			X		
b) The submission includes sterility and/or reprocessing information that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness.	X				
F. Shelf Life					
24) Proposed shelf life/expiration date stated **OR** Statement that shelf-life is not applicable because of low likelihood of time-dependent product degradation	X				
25) For a sterile device, submission includes summary of methods used to establish that device packaging will maintain a sterile barrier for the entirety of the proposed shelf life.	X				

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
26) Submission includes summary of methods used to establish that device performance is maintained for the entirety of the proposed shelf-life (e.g., mechanical properties, coating integrity, pH, osmolality, etc.). **OR** Statement why performance data is not needed to establish maintenance of device performance characteristics over the shelf-life period.	X				
G. Biocompatibility					
If an vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.					
Submission states that there: (one of the below must be checked)					
X Are direct or indirect patient-contacting components.					
Are no direct or indirect patient-contacting components.					
Information regarding patient contact status of the device is not provided (if this box checked, please also check one of the two boxes below).					
Patient contact information not needed for this device (e.g., software-only device)					
Patient contact information needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
27) Submission includes a list identifying each of patient-contacting device component (e.g., implant, delivery catheter) and associated materials of construction for each component, including identification of color additives, if present.	X				
28) Submission identifies contact classification (e.g., surface-contacting, less then 24 hour duration) for each patient-contacting device component (e.g., implant, delivery catheter)	X				
29) Biocompatibility assessment of patient-contacting components Submission includes: Test protocol (including identification and description of test article), methods, pass/fail criteria, and results provided for each completed test. **OR** A statement that biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate).	X				
H. Software					
Submission states that the device: (one of the below must be checked)					
Does contain software/firmware					
X Does not contain software/firmware					
Information on whether device contains software/firmware is not provided. (If this box is checked, please also check one of the two boxes below.)					
Software/firmware information not needed for this device (e.g., surgical suture, condom)					
Software/firmware information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
I. Electrical Safety and EMC					
Electrical Safety Submission states that the device: (one of the below must be checked)					
Does require electrical safety evaluation					
X Does not require electrical safety evaluation					
Information on whether device requires electrical safety evaluation is not provided. (If this box is checked, please also check one of the two boxes below.)					
Electrical safety information not needed for this device (e.g., surgical suture, condom)					
Electrical safety information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
EMC Submission states that the device: (one of the below must be checked)					
Does require EMC evaluation					
X Does not require EMC evaluation					
Information on whether device requires EMC evaluation is not provided. (If this box is checked, please also check one of the two boxes below.)					
EMC information not needed for this device (e.g., surgical suture, condom)					
EMC information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
J. Performance Data - General					
If an in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from checklist if "N/A" is selected. Performance data criteria relating to IVD devices is addressed in Section K.					
34) Full test report is provided for each completed test. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre-defined pass/fail criteria, results summary, conclusions.	X				
a) Submission includes an explanation of how the data generated from each test report supports a finding of substantial equivalence (e.g., comparison to predicate device testing, dimensional analysis, etc.).	X				
35) The device has a device-specific guidance document, special controls document, and/ or requirements in a device-specific regulation regarding performance data that is applicable to the subject device.	X				
a) The submission addresses performance data recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria.			X		

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
b) The submission includes performance data that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness.	X				
36) If literature is referenced in the submission, submission includes:			X		
37) For each completed animal study, the submission provides the following:			X		
K. Performance Characteristics - In Vitro Diagnostic Devices Only **(Also see 21 CFR 809.10(b)(12))**					
Submission states that the device: (one of the below must be checked)					
is an in vitro diagnostic device.					
X is not an in vitro diagnostic device.					
If "is not" is selected, the performance data-related criteria below are omitted from the checklist.					

Decision: ○ Accept ◉ Refuse to Accept

If Accept, notify applicant.

If Refuse to Accept, notify applicant electronically and include a copy of this checklist.

Digital Signature Concurrence Table	
Reviewer Sign-Off	Andrew I. Steen -S 2015.11.04 13:34:22 -05'00'
Branch Chief Sign-Off (digital signature optional)*	
Division Sign-Off (digital signature optional)*	

* Branch and Division review of checklist and concurrence with decision required. Branch and Division digital signature optional.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

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

K153064
Blue Sky Bio, LLC
Device Trade Name: Blue Sky Bio Zygomatic Impant System
Contact Name: Kevin Thomas

DEFICIENCY LIST

(b)(4)

(b)(4)

(b)(4)

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DEFICIENCY LIST

(b)(4)

(b)(4)

(b)(4)

From: Kevin Thomas [mailto:kthomas@paxmed.com]
Sent: Thursday, April 28, 2016 5:37 PM
To: Steen, Andrew I
Cc: Floyd Larson
Subject: K153064, Blue Sky Bio Zygomatic, revised 510(k) Summary

Dear Andrew,
Thank you for the call today regarding the 510(k) Summary for K153064. I have attached the revised summary as we discussed.

(b)(4)

Thank you again for your assistance with this submission.

Best regards,

Kevin

Kevin A. Thomas, PhD
Vice President and Director of Regulatory Affairs
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, CA 92130

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510(k) Summary

Blue Sky Bio, LLC

Blue Sky Bio Zygomatic Implant System

April 28, 2016

ADMINISTRATIVE INFORMATION

Manufacturer Name	Blue Sky Bio, LLC 888 E Belvidere Road, Suite 212 Grayslake, IL 60030 Telephone +1 718-376-0422 Fax +1 888-234-3685
Official Contact	Michele Vovolka Vice President of RA/QA
Representative/Consultant	Kevin A. Thomas, PhD Linda K. Schulz, BSDH, RDH PaxMed International, LLC 12264 El Camino Real, Suite 400 San Diego, CA 92130 Telephone: +1 (858) 792-1235 Fax: +1 (858) 792-1236 Email: kthomas@paxmed.com lschulz@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	Blue Sky Bio Zygomatic Implant System
Common Name	Endosseous dental implant Endosseous dental implant abutment
Classification Regulations	21 CFR 872.3640
Product Code	DZE NHA
Classification Panel	Dental Products Panel
Reviewing Branch	Dental Devices Branch

PREDICATE DEVICE INFORMATION

Primary predicate device:
K141777, Neodent Implant System, JJGC Indústria e Comércio de Materiais Dentários SA

Reference predicate devices:
K102034, Blue Sky Bio Dental Implant System, Blue Sky Bio, LLC
K060957, Blue Sky Bio Dental Implant System, Blue Sky Bio, LLC
K093562, Zygomatic Implant System, Southern Implants, Inc.

INTENDED USE

Blue Sky Bio Zygomatic Implant System is indicated for surgical installation in the zygoma region, in cases of severe jaw resorption, in order to restore patient esthetics and chewing function. Blue Sky Bio zygomatic implants are recommended for the posterior (pre-molar/molar) region, one implant on each side, with at least two standard dental implants in the anterior region to support a fixed restoration. Blue Sky Bio zygomatic implants may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.

DEVICE DESCRIPTION

Blue Sky Bio Zygomatic Implant System submission includes threaded root-form dental implants and mating abutments designed for placement into the zygomatic bone. The zygomatic implants are provided with an internal hexagon connection and a tapered internal hexagon interface for connection to the subject abutments. The internal hexagon connection implants are provided with a body diameter of 4.7 mm and platform diameters of 3.5 mm and 4.5 mm. The tapered internal hexagon connection implants are provided with a body diameter of 4.3 mm and a narrow platform (NP) connection, and with a body diameter of 5.0 mm with a regular platform (RP) connection. All implants are provided in multiple overall threaded lengths ranging from 35 mm to 55 mm. This submission includes mating abutments with platform diameters of 3.5, 4.3, and 4.5 mm, and each abutment diameter is provided with 17° and 30° of angulation. All subject device abutments are for support of screw-retained overdenture prosthetic restorations. The abutment screws compatible with the subject device abutments were cleared in K060957 and K102034. The subject device zygomatic implants and abutments are made of titanium alloy conforming to ASTM F136 *Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401).* The previously cleared abutment screws also are made of material conforming to ASTM F136.

PERFORMANCE DATA

Non-clinical data submitted, referenced, or relied upon to demonstrate substantial equivalence include: biocompatibility (referenced from K102034 and K060957), engineering analysis, dimensional analysis, and dynamic compression-bending testing of the Taper Hex 4.3 mm body diameter implant with the NP platform according to ISO 14801 *Dentistry – Implants – Dynamic fatigue test for endosseous dental implants.* No clinical data were included in this submission.

EQUIVALENCE TO MARKETED DEVICE

Blue Sky Bio, LLC submits the following information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, the subject device is substantially equivalent in indications and design principles to the following legally marketed predicate devices:

K141777, Neodent Implant System, JJGC Indústria e Comércio de Materiais Dentários SA;

K102034, Blue Sky Bio Dental Implant System, Blue Sky Bio, LLC;

K060957, Blue Sky Bio Dental Implant System, Blue Sky Bio, LLC; and

K093562, Zygomatic Implant System, Southern Implants, Inc.

A comparison of the technological characteristics of the subject device and the primary predicate device K141777 is provided in the following table.

	Subject Device	**Primary Predicate Device**
Comparison	Blue Sky Bio, LLC Blue Sky Bio Zygomatic Implant System K153064	JJGC Indústria e Comércio de Materiais Dentários SA Neodent Implant System K141777
Indications for Use	Blue Sky Bio Zygomatic Implant System is indicated for surgical installation in the zygoma region, in cases of severe jaw resorption, in order to restore patient esthetics and chewing function. Blue Sky Bio zygomatic implants are recommended for the posterior (pre-molar/molar) region, one implant on each side, with at least two standard dental implants in the anterior region to support a fixed restoration. Blue Sky Bio zygomatic implants may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.	Zygomatic Implants are indicated for surgical installation in the zygoma region, in cases of severe jaw resorption, in order to restore patient esthetics and chewing function. Zygomatic Implants are recommended for the posterior (pre-molar/molar) region, one implant on each side, with at least two standard dental implants in the anterior region to support a fixed restoration. Zygomatic Implants may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.
Implants		
Design	Threaded root-form implant to be used with mating abutments	Threaded root-form implant to be used with mating abutments
Implant body Ø and Platform Ø	Internal hex connection Implant body Ø: 4.7 mm Abutment platform Ø: 3.5 mm, 4.5 mm (implant body tapers at apical portion)	External hex and Morse taper Implant body Ø: 4.4 mm tapering to 3.9 mm Platform Ø: 4.1 mm
	Tapered internal hex connection Implant body Ø: 4.3 mm with NP 3.5 mm abutment platform Implant body Ø: 5.0 mm with RP 4.3 mm abutment platform (implant body tapers at apical portion)	
Implant Lengths	All implants: 35, 37.5, 40, 42.5, 45, 47.5, 50, 52.5, 55 mm	External hex: 30, 35, 40, 45, 47.5, 50, 52.5 mm Morse taper: 30, 35, 40, 42.5, 45, 47.5, 50, 52.5 mm
Implant-Abutment Interface		
Type	Internal hex with 12° taper Internal hex with 45° bevel	External hex Morse taper
Implant body-abutment connection angle	n/a	45°
Abutments		
Platform Diameter	Internal hex connection: 3.5 mm, 4.5 mm Tapered internal hex connection: 4.3 mm	4.1 mm
Abutment Angle	17°, 30°	0° (straight)

	Subject Device	Primary Predicate Device
Comparison	Blue Sky Bio, LLC Blue Sky Bio Zygomatic Implant System K153064	JJGC Indústria e Comércio de Materiais Dentários SA Neodent Implant System K141777
Materials		
Implants	Ti-6Al-4V	F67 unalloyed titanium, grade 4
Implant Surface	Grit blasted and acid etched	Machined
Abutments	Ti-6Al-4V	F136 Ti-6Al-4V ELI
Abutment Screws	Ti-6Al-4V	External hex: F136 Ti-6Al-4V ELI

The subject device and the primary predicate K141777 have substantially equivalent indications for use, including restoration of patient esthetics and chewing function, and immediate loading when used with standard dental implants placed in the anterior region to support a fixed restoration. The implants of the subject device and the predicate device K141777 have similar designs and dimensions, including lengths appropriate for zygomatic placement.

The subject zygomatic implants are very similar in design to endosseous dental implants from Blue Sky Bio cleared in K102034 and K060957, except for a slight change in the endosseous thread and the longer lengths appropriate for zygomatic placement. The subject zygomatic implants are provided in a range of implant body diameters (maximum endosseous thread diameters) of 4.3 mm to 5.0 mm, the same as the predicate implants cleared in K102034 and K060957. The smaller subject device implant body (4.3 mm diameter) as compared to the primary predicate K141777 (4.4 mm diameter) is supported by the reference predicate K093562 (4.05 mm body diameter), and by and dynamic compression-bending testing according to ISO 14801.

The subject device implants are provided in the same range of overall lengths as the primary predicate K141777 (35 mm to 52.5 mm), and the subject device 55 mm length implant is supported by the reference predicate K093562.

This submission includes abutments with an internal hexagon and tapered internal hexagon interfaces for connection to the subject zygomatic implants. The subject device abutments are provided with platform diameters of 3.5, 4.3, and 4.5 mm, and angulation of 17° or 30°. The subject device abutments are substantially equivalent to the abutments cleared in K102034 and K060957 in terms of implant-abutment connections, platform diameters, angulation, and materials. The subject abutments are to be used with compatible abutment screws cleared in K102034 and K060957.

Differences between the subject device and the primary predicate K141777 include the location of angulation correction (subject device includes abutments with angulation, versus K141777 implant designs included angulation at the abutment-implant connection), and the amount of angulation (subject device 17° or 30°, versus K141777 only 45°). These differences between the subject device and the primary predicate are supported by dynamic compression-bending testing according to ISO 14801. Dynamic testing of worst case subject device constructs consisting of the smallest diameter implant (Taper Hex 4.3 mm body diameter) and largest angulation (30°)

demonstrated fatigue performance substantially equivalent to that of the primary predicate K141777.

The subject device implants and abutments are made of titanium alloy conforming to ASTM F136 *Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)*, the same as these components cleared in K102034 and K060957. The endosseous surface finish of the subject device implants is the same as the predicate implants cleared in K102034 and K060957.

The subject device implants have similar packaging and are sterilized using the same materials and processes as described in K102034 and K060957. The subject device abutments are provided nonsterile in similar packaging and are to be sterilized using the same processes as described in K102034 and K060957.

CONCLUSION

The subject device and the predicate devices have the same intended use, have similar technological characteristics, and are made of similar materials. The subject device and predicate devices encompass the same range of physical dimensions, including diameter and length of the implants, and the diameter and angulation of the abutments. The subject and predicate devices are packaged in similar materials and sterilized using similar methods.

The data included in this submission demonstrate substantial equivalence to the predicate devices listed above.

Food and Drug Administration
CDRH/ODE/DAGRID/DEDB
WO66 RMG312
10903 New Hampshire Ave
301-796-6284

Premarket Notification [510(k)] Review

Date: April 27, 2016

Reviewer: Andrew I. Steen, Mechanical Engineer

Subject: Traditional 510(k)# K153064/S002

Applicant: Blue Sky Bio, LLC	**Device Trade Name:** Blue Sky Bio Zygomatic Implant System
Contact Name: Kevin Thomas	**Contact Title:** Regulatory Affairs
Correspondent Firm: Paxmed International, LLC	**Phone:** 1 (858) 792-1235 **Email:** kthomas@paxmed.com
Received Date: March 31, 2016	**Due Date:** April 30, 2016
Reg #: 872.3640 **Reg Name:** Endosseous Dental Implant	**Class:** II **Product Code(s):** DZE
Reg #: 872.3630 Reg Name: Endosseous dental implant abutment	Class: II Product Code(s): NHA

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Owner
K141777	DZE, NHA	Neodent Implant System	Jjgc Industria E Comercio De Materiais Dentarios S
K102034	DZE, NHA	Blue Sky Bio Dental Implant System	Blue Sky Bio, LLC
K060957	DZE	Modification To Blue Sky Bio Dental Implant System	Blue Sky Bio, LLC
K093562	DZE	Endosseous Dental Implant	Southern Implants, Inc.

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Digital Signature Concurrence Table	
Reviewer Sign-Off	

	Andrew I. Steen -S 2016.04.27 10:10:15 -04'00'

From: Kevin Thomas [mailto:kthomas@paxmed.com]

Sent: Thursday, April 28, 2016 5:37 PM

To: Steen, Andrew I

Cc: Floyd Larson

Subject: K153064, Blue Sky Bio Zygomatic, revised 510(k) Summary

Dear Andrew,

Thank you for the call today regarding the 510(k) Summary for K153064. I have attached the revised summary as we discussed.

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Thank you again for your assistance with this submission.

Best regards,

Kevin

Kevin A. Thomas, PhD

Vice President and Director of Regulatory Affairs

PaxMed International, LLC

12264 El Camino Real, Suite 400

San Diego, CA 92130

Phone 858-792-1235 (Ext. 309)

877-792-1235 (toll free In the US)

Fax 858-792-1236

Skype (b)(6)

www.paxmed.com<http://www.paxmed.com/>

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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

Blue Sky Bio, LLC
% Kevin A. Thomas, Ph.D.
Regulatory Affairs
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130

Re: K153064
Trade/Device Name: Blue Sky Bio Zygomatic Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: March 31, 2016
Received: March 31, 2016

Dear Dr. Thomas:

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K153064

Device Name

Blue Sky Bio Zygomatic Implant System

Indications for Use *(Describe)*

Blue Sky Bio Zygomatic Implant System is indicated for surgical installation in the zygoma region, in cases of severe jaw resorption, in order to restore patient esthetics and chewing function. Blue Sky Bio zygomatic implants are recommended for the posterior (pre-molar/molar) region, one implant on each side, with at least two standard dental implants in the anterior region to support a fixed restoration. Blue Sky Bio zygomatic implants may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
CDRH/ODE/DAGRID/DEDB
WO66 RMG312
10903 New Hampshire Ave
301-796-6284

Premarket Notification [510(k)] Review

Date: January 5, 2016

Reviewer: Andrew I. Steen, Mechanical Engineer

Subject: Traditional 510(k)# K153064/S001

Applicant: Blue Sky Bio, LLC	**Device Trade Name:** Blue Sky Bio Zygomatic Impant System
Contact Name: Kevin Thomas	**Contact Title:** Regulatory Affairs
Correspondent Firm: Paxmed International, LLC	**Phone:** 1 (858) 792-1235 **Email:** kthomas@paxmed.com
Received Date: November 6, 2015	**Due Date:** February 4, 2016
Reg #: 872.3640 **Reg Name:** Endosseous Dental Implant	**Class:** II **Product Code(s):** DZE
Reg #: 872.3630 Reg Name: Endosseous dental implant abutment	Class: II Product Code(s): NHA

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Owner
K141777	DZE, NHA	Neodent Implant System	Jjgc Industria E Comercio De Materiais Dentarios S
K102034	DZE, NHA	Blue Sky Bio Dental Implant System	Blue Sky Bio, LLC
K060957	DZE	Modification To Blue Sky Bio Dental Implant System	Blue Sky Bio, LLC
K093562	DZE	Endosseous Dental Implant	Southern Implants, Inc.

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DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

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

April 29, 2016

Blue Sky Bio, LLC
c/o Kevin A. Thomas, Ph.D.
Regulatory Affairs
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130

Re: K153064
Trade/Device Name: Blue Sky Bio Zygomatic Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: March 31, 2016
Received: March 31, 2016

Dear Dr. Thomas:

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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 Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

November 18, 2015</br></br>

Acceptance Review Notification - Accepted

An administrative acceptance review was conducted on your premarket notification (510(k)) K153064/S001, and it was found to contain all of the necessary elements and information needed to proceed with the substantive review. We will contact you should we require any additional information during the course of the substantive review. The lead reviewer assigned to your submission is Andrew Steen.

 *** This is a system-generated email notification ***

January 5, 2016</br></br> We have reviewed your submission K153064/S001 and have determined that additional information is required. Your file is being placed on hold pending a complete response to the attached deficiencies.

Please submit your response, referencing the submission number K153064/S001 to:

U.S. Food and Drug Administration

Center for Devices and Radiological Health

Document Control Center - WO66-G609

10903 New Hampshire Avenue

Silver Spring, MD 20993-0002

Please refer to the eCopy guidance at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf for current information on the number of copies and the format (paper versus eCopy) you must submit.

Your response is due within 180 days from the date of this request, which is July 3, 2016. If a complete response is not received in CDRH's Document Control Center within 180 days, we will consider this submission to be withdrawn, and we will delete it from our review system.

You may not market this device until you have received a letter from FDA allowing you to do so. If you market the device without FDA clearance, you will be in violation of the Federal Food, Drug, and Cosmetic Act.

If you would like a meeting or teleconference with the review team and management to discuss your planned approach for responding to the attached deficiencies, please submit your request for feedback as a Submission Issue Q-Submission (Q-Sub). Please note that a Submission Issue Q-Sub does not take the place of a formal response to this email notification. As noted above, FDA will consider this submission to be withdrawn if FDA does not receive, in a submission to the Document Control Center, a complete response to all of the attached deficiencies within 180 calendar days of the date of this request.

Should you have questions about this email, you may contact Andrew Steen, the lead reviewer assigned to your submission.

 *** This is a system-generated email notification ***

Public Health Service

Food and Drug Administration
CDRH/ODE/DAGRID/DEDB
WO66 RMG312
10903 New Hampshire Ave
301-796-6284

Premarket Notification [510(k)] Review

Date: January 5, 2016

Reviewer: Andrew I. Steen, Mechanical Engineer

Subject: Traditional 510(k)# K153064/S001

Applicant: Blue Sky Bio, LLC	**Device Trade Name:** Blue Sky Bio Zygomatic Impant System
Contact Name: Kevin Thomas	**Contact Title:** Regulatory Affairs
Correspondent Firm: Paxmed International, LLC	**Phone:** 1 (858) 792-1235 **Email:** kthomas@paxmed.com
Received Date: November 6, 2015	**Due Date:** February 4, 2016
Reg #: 872.3640 **Reg Name:** Endosseous Dental Implant	**Class:** II **Product Code(s):** DZE
Reg #: 872.3630 Reg Name: Endosseous dental implant abutment	Class: II Product Code(s): NHA

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Owner
K141777	DZE, NHA	Neodent Implant System	Jjgc Industria E Comercio De Materiais Dentarios S
K102034	DZE, NHA	Blue Sky Bio Dental Implant System	Blue Sky Bio, LLC
K060957	DZE	Modification To Blue Sky Bio Dental Implant System	Blue Sky Bio, LLC
K093562	DZE	Endosseous Dental Implant	Southern Implants, Inc.

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Reviewer Sign-Off	Andrew I. Steen -S 2016.01.05 11:57:19 -05'00'

510(k) Summary

Blue Sky Bio, LLC

Blue Sky Bio Zygomatic Implant System

April 28, 2016

ADMINISTRATIVE INFORMATION

Manufacturer Name	Blue Sky Bio, LLC 888 E Belvidere Road, Suite 212 Grayslake, IL 60030 Telephone +1 718-376-0422 Fax +1 888-234-3685
Official Contact	Michele Vovolka Vice President of RA/QA
Representative/Consultant	Kevin A. Thomas, PhD Linda K. Schulz, BSDH, RDH PaxMed International, LLC 12264 El Camino Real, Suite 400 San Diego, CA 92130 Telephone: +1 (858) 792-1235 Fax: +1 (858) 792-1236 Email: kthomas@paxmed.com lschulz@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	Blue Sky Bio Zygomatic Implant System
Common Name	Endosseous dental implant Endosseous dental implant abutment
Classification Regulations	21 CFR 872.3640
Product Code	DZE NHA
Classification Panel	Dental Products Panel
Reviewing Branch	Dental Devices Branch

PREDICATE DEVICE INFORMATION

Primary predicate device:
K141777, Neodent Implant System, JJGC Indústria e Comércio de Materiais Dentários SA

Reference predicate devices:
K102034, Blue Sky Bio Dental Implant System, Blue Sky Bio, LLC
K060957, Blue Sky Bio Dental Implant System, Blue Sky Bio, LLC
K093562, Zygomatic Implant System, Southern Implants, Inc.

INTENDED USE

Blue Sky Bio Zygomatic Implant System is indicated for surgical installation in the zygoma region, in cases of severe jaw resorption, in order to restore patient esthetics and chewing function. Blue Sky Bio zygomatic implants are recommended for the posterior (pre-molar/molar) region, one implant on each side, with at least two standard dental implants in the anterior region to support a fixed restoration. Blue Sky Bio zygomatic implants may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.

DEVICE DESCRIPTION

Blue Sky Bio Zygomatic Implant System submission includes threaded root-form dental implants and mating abutments designed for placement into the zygomatic bone. The zygomatic implants are provided with an internal hexagon connection and a tapered internal hexagon interface for connection to the subject abutments. The internal hexagon connection implants are provided with a body diameter of 4.7 mm and platform diameters of 3.5 mm and 4.5 mm. The tapered internal hexagon connection implants are provided with a body diameter of 4.3 mm and a narrow platform (NP) connection, and with a body diameter of 5.0 mm with a regular platform (RP) connection. All implants are provided in multiple overall threaded lengths ranging from 35 mm to 55 mm. This submission includes mating abutments with platform diameters of 3.5, 4.3, and 4.5 mm, and each abutment diameter is provided with 17° and 30° of angulation. All subject device abutments are for support of screw-retained overdenture prosthetic restorations. The abutment screws compatible with the subject device abutments were cleared in K060957 and K102034. The subject device zygomatic implants and abutments are made of titanium alloy conforming to ASTM F136 *Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401).* The previously cleared abutment screws also are made of material conforming to ASTM F136.

PERFORMANCE DATA

Non-clinical data submitted, referenced, or relied upon to demonstrate substantial equivalence include: biocompatibility (referenced from K102034 and K060957), engineering analysis, dimensional analysis, and dynamic compression-bending testing of the Taper Hex 4.3 mm body diameter implant with the NP platform according to ISO 14801 *Dentistry – Implants – Dynamic fatigue test for endosseous dental implants.* No clinical data were included in this submission.

EQUIVALENCE TO MARKETED DEVICE

Blue Sky Bio, LLC submits the following information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, the subject device is substantially equivalent in indications and design principles to the following legally marketed predicate devices:

K141777, Neodent Implant System, JJGC Indústria e Comércio de Materiais Dentários SA;

K102034, Blue Sky Bio Dental Implant System, Blue Sky Bio, LLC;

K060957, Blue Sky Bio Dental Implant System, Blue Sky Bio, LLC; and

K093562, Zygomatic Implant System, Southern Implants, Inc.

A comparison of the technological characteristics of the subject device and the primary predicate device K141777 is provided in the following table.

	Subject Device	**Primary Predicate Device**
Comparison	Blue Sky Bio, LLC Blue Sky Bio Zygomatic Implant System K153064	JJGC Indústria e Comércio de Materiais Dentários SA Neodent Implant System K141777
Indications for Use	Blue Sky Bio Zygomatic Implant System is indicated for surgical installation in the zygoma region, in cases of severe jaw resorption, in order to restore patient esthetics and chewing function. Blue Sky Bio zygomatic implants are recommended for the posterior (pre-molar/molar) region, one implant on each side, with at least two standard dental implants in the anterior region to support a fixed restoration. Blue Sky Bio zygomatic implants may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.	Zygomatic Implants are indicated for surgical installation in the zygoma region, in cases of severe jaw resorption, in order to restore patient esthetics and chewing function. Zygomatic Implants are recommended for the posterior (pre-molar/molar) region, one implant on each side, with at least two standard dental implants in the anterior region to support a fixed restoration. Zygomatic Implants may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.
Implants		
Design	Threaded root-form implant to be used with mating abutments	Threaded root-form implant to be used with mating abutments
Implant body Ø and Platform Ø	Internal hex connection Implant body Ø: 4.7 mm Abutment platform Ø: 3.5 mm, 4.5 mm (implant body tapers at apical portion)	External hex and Morse taper Implant body Ø: 4.4 mm tapering to 3.9 mm Platform Ø: 4.1 mm
	Tapered internal hex connection Implant body Ø: 4.3 mm with NP 3.5 mm abutment platform Implant body Ø: 5.0 mm with RP 4.3 mm abutment platform (implant body tapers at apical portion)	
Implant Lengths	All implants: 35, 37.5, 40, 42.5, 45, 47.5, 50, 52.5, 55 mm	External hex: 30, 35, 40, 45, 47.5, 50, 52.5 mm Morse taper: 30, 35, 40, 42.5, 45, 47.5, 50, 52.5 mm
Implant-Abutment Interface		
Type	Internal hex with 12° taper Internal hex with 45° bevel	External hex Morse taper
Implant body-abutment connection angle	n/a	45°
Abutments		
Platform Diameter	Internal hex connection: 3.5 mm, 4.5 mm Tapered internal hex connection: 4.3 mm	4.1 mm
Abutment Angle	17°, 30°	0° (straight)

	Subject Device	Primary Predicate Device
Comparison	Blue Sky Bio, LLC Blue Sky Bio Zygomatic Implant System K153064	JJGC Indústria e Comércio de Materiais Dentários SA Neodent Implant System K141777
Materials		
Implants	Ti-6Al-4V	F67 unalloyed titanium, grade 4
Implant Surface	Grit blasted and acid etched	Machined
Abutments	Ti-6Al-4V	F136 Ti-6Al-4V ELI
Abutment Screws	Ti-6Al-4V	External hex: F136 Ti-6Al-4V ELI

The subject device and the primary predicate K141777 have substantially equivalent indications for use, including restoration of patient esthetics and chewing function, and immediate loading when used with standard dental implants placed in the anterior region to support a fixed restoration. The implants of the subject device and the predicate device K141777 have similar designs and dimensions, including lengths appropriate for zygomatic placement.

The subject zygomatic implants are very similar in design to endosseous dental implants from Blue Sky Bio cleared in K102034 and K060957, except for a slight change in the endosseous thread and the longer lengths appropriate for zygomatic placement. The subject zygomatic implants are provided in a range of implant body diameters (maximum endosseous thread diameters) of 4.3 mm to 5.0 mm, the same as the predicate implants cleared in K102034 and K060957. The smaller subject device implant body (4.3 mm diameter) as compared to the primary predicate K141777 (4.4 mm diameter) is supported by the reference predicate K093562 (4.05 mm body diameter), and by and dynamic compression-bending testing according to ISO 14801.

The subject device implants are provided in the same range of overall lengths as the primary predicate K141777 (35 mm to 52.5 mm), and the subject device 55 mm length implant is supported by the reference predicate K093562.

This submission includes abutments with an internal hexagon and tapered internal hexagon interfaces for connection to the subject zygomatic implants. The subject device abutments are provided with platform diameters of 3.5, 4.3, and 4.5 mm, and angulation of 17° or 30°. The subject device abutments are substantially equivalent to the abutments cleared in K102034 and K060957 in terms of implant-abutment connections, platform diameters, angulation, and materials. The subject abutments are to be used with compatible abutment screws cleared in K102034 and K060957.

Differences between the subject device and the primary predicate K141777 include the location of angulation correction (subject device includes abutments with angulation, versus K141777 implant designs included angulation at the abutment-implant connection), and the amount of angulation (subject device 17° or 30°, versus K141777 only 45°). These differences between the subject device and the primary predicate are supported by dynamic compression-bending testing according to ISO 14801. Dynamic testing of worst case subject device constructs consisting of the smallest diameter implant (Taper Hex 4.3 mm body diameter) and largest angulation (30°)

demonstrated fatigue performance substantially equivalent to that of the primary predicate K141777.

The subject device implants and abutments are made of titanium alloy conforming to ASTM F136 *Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)*, the same as these components cleared in K102034 and K060957. The endosseous surface finish of the subject device implants is the same as the predicate implants cleared in K102034 and K060957.

The subject device implants have similar packaging and are sterilized using the same materials and processes as described in K102034 and K060957. The subject device abutments are provided nonsterile in similar packaging and are to be sterilized using the same processes as described in K102034 and K060957.

CONCLUSION

The subject device and the predicate devices have the same intended use, have similar technological characteristics, and are made of similar materials. The subject device and predicate devices encompass the same range of physical dimensions, including diameter and length of the implants, and the diameter and angulation of the abutments. The subject and predicate devices are packaged in similar materials and sterilized using similar methods.

The data included in this submission demonstrate substantial equivalence to the predicate devices listed above.

Contains Nonbinding Recommendations

Print Form

Acceptance Checklist for Traditional 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.
FDA recommends that the submitter include this completed checklist as part of the submission.

510(k) #: K153064 Date Received by DCC: Oct 22, 2015

Lead Reviewer: Andrew I. Steen Trade Name: Blue Sky Bio Zygomatic Implant System

Branch: DEDB Division: DAGRID Center/Office: CDRH/ODE

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means the reviewer did not assess the element during the RTA review and that the element will be assessed during substantive review.

IMPORTANT - Many checklist elements include additional details regarding information to address the element that can be seen by hovering over the element (Example - Element 4 in Section A of the checklist).

Preliminary Questions Answers in the shaded blocks indicate consultation with a Center advisor is needed. (Boxes checked in this section represent FDAs preliminary assessment of these questions at the time of administrative review.)	Yes	No	N/A
1) Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)? If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Product Jurisdiction Liaison to determine the appropriate action, and inform division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If the product does not appear to be a device or such a combination product, mark "No."	X		
Comments:			
2. Is the submission with the appropriate Center? If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the submission is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or CBER Product Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If submission should not be reviewed by your Center mark "No."	X		
Comments:			
3) If a Request for Designation (RFD) was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following: **a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission?** **b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission?** If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Product Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide summary of Jurisdictional Officer's/Liaison's determination.* If the answer to either question above is no, mark "No." If there was no RFD, mark "N/A."			
Comments:			

4) Is this device type eligible for a 510(k) submission? If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), you should consult with the CDRH 510(k) Program Director or appropriate CBER staff during the acceptance review. If 510(k) is not the appropriate regulatory submission, mark "No."	X		
Comments:			
5) Is there a pending PMA for the same device with the same indications for use? If yes, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.		X	
Comments:			
6) If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If yes, consult with the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action. Check on web at http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm If no clinical studies have been submitted, mark "N/A."			
Comments:			

- If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and issue the "Original Jurisdictional Product" letter.
- If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Jurisdictional Officer or CBER Office of Jurisdiction Liaison.
- If the answer to 4 is "No," the lead reviewer should consult division management and other Center resources to determine the appropriate action.
- If the answer to 5 is "Yes," then stop review of the 510(k), contact the CDRH 510(k) Staff and PMA Staff, or appropriate CBER staff.
- If the answer to 6 is "Yes," then contact CDRH/OC/DBM or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with DBM or BMB Staff, and indicate their recommendation/action.

Organizational Elements

Failure to include these items should not result in an RTA designation.

*Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	*Page #
1) Submission contains a Table of Contents	X		
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	X		
3) All pages of the submission are numbered.	X		
4) Type of 510(k) is identified (i.e., Traditional, Abbreviated, or Special).	X		
Comments:			

Elements of a Complete Submission (RTA Items)
(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

- Any "No" answer will result in a "Refuse to Accept" decision; however, FDA staff has discretion to determine whether missing items are needed to ensure that the submission is administratively complete to allow the submission to be accepted or to request missing checklist items interactively from submitters during RTA review.
- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
A. Administrative					
1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	X				
2) Submission identifies the following (FDA recommends use of the CDRH Premarket Review Submission Cover Sheet form [Form 3514]):					
a) Device trade/proprietary name	X				
b) Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	X				
3) Submission contains an Indication for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109, and FDA's guidance "Alternative to Certain Prescription Devices Labeling Requirements.") *See recommended format. (http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM360431.pdf).*	X				
4) Submission contains a 510(k) Summary or 510(k) Statement.	X				
5) Submission contains a Truthful and Accuracy Statement per 21 CFR 807.87(k) *See recommended format.* *(http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142707.htm).*	X				
6) Submission is a Class III 510(k) device.			X		
7) Submission contains clinical data			X		
8) The submission identifies prior submissions for the same device included in the current submission (e.g., submission numbers for a prior not substantially equivalent [NSE] determination, prior deleted or withdrawn 510(k), Pre-Submission, IDE, PMA, etc.). **OR** States that there were no prior submissions for the subject device.	X				
a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence from prior submissions for this device are addressed.			X		
B. Device Description					
9) The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding device description that is applicable to the subject device.					
a) The submission addresses device description recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria.			X		

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
b) The submission includes device description information that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness.	X				
10) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling).	X				
11) The submission includes descriptive information for the device, including the following:					
a) A description of the principle of operation or mechanism of action for achieving the intended effect.	X				
b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	X				
c) A list and description of each device for which clearance is requested.	X				
d) Submission contains representative engineering drawing(s), schematics, illustrations, photos and/or figures of the device. **OR** Submission includes a statement that engineering drawings, schematics, etc. are not applicable to the device (e.g., device is a reagent and figures are not pertinent to describe the device).	X				
12) Device is intended to be marketed with multiple components, accessories, and/or as part of a system.	X				
a) Submission includes a list of all components and accessories to be marketed with the subject device.	X				
b) Submission includes a description (as detailed in item 11(a), 11(b) and 11(d) above) of each component or accessory.	X				
c) A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance **AND** A statement is provided that identifies components or accessories that have not received prior 510(k) clearance.	X				
C. Substantial Equivalence Discussion					
13) Submitter has identified a predicate device(s), including the following information:					
a) Predicate device identifier provided (e.g., 510(k) number, de novo number, reclassified PMA number, regulation number if exempt or statement that the predicate is a preamendment device). For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding documenting preamendment status is available online. (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/MedicalDeviceQualityandCompliance/ucm379552.htm).*	X				

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
b) The identified predicate(s) is consistent throughout the submission (e.g., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing).	X				
14) Submission includes a comparison of the following for the predicate(s) and subject device and a discussion why any differences between the subject and predicate(s) do not impact safety and effectiveness [see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)] *See "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" guidance document for more information on comparing intended use and technological characteristics.*					
a) Indications for Use	X				
b) Technology, including features, materials, and principles of operation	X				
D. Proposed Labeling (see also 21 CFR part 801 and 809 as applicable)					
15) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual).	X				
a) Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided).	X				
b) Labeling includes: - Statements of conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) (21 CFR 801.5) **AND** - Includes adequate directions for use (see 21 CFR 801.5) **OR** - Submission states that device qualifies for exemption per 21 CFR 801 Subpart D	X				
16) Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1).	X				
17) Labeling includes the prescription statement [see 21 CFR 801.109(b)(1)] or Rx Only symbol (see also Section 502(a) of the FD&C Act and FDA's guidance "Alternative to Certain Prescription Device Labeling Requirements").	X				
18) The device has a device-specific guidance document, special controls document, and/ or requirements in a device-specific regulation regarding labeling that is applicable to the subject device.					
a) The submission addresses labeling recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria.			X		
b) The submission includes labeling information that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness.	X				

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
19) If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10.			X		
E. Sterilization					
If an *in vitro* diagnostic (IVD) device and sterilization is not applicable, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.					
Submission states that the device, and/or accessories, and/or components are: (one of the below must be checked)					
X Provided sterile, intended to be single-use					
X Requires processing during its use-life					
Non-sterile when used (and no processing required)					
Information regarding the sterility status of the device is not provided. (If this box is checked, please also check one of the two boxes below.)					
Sterility status not needed for this device (e.g., software-only device)					
Sterility status needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *Please refer to the guidance document titled "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" for additional information.*					
20) Assessment of the need for cleaning and subsequent disinfection or sterilization information					
a) Identification of device, and/or accessories, and/or components that are provided sterile.	X				
b) Identification of device, and/or accessories, and/or components that are end user sterilized or disinfected.	X				
c) Identification of device, and/or accessories, and/or components that are reusable.			X		
21) If the device, and/or accessory, and/or a component is provided sterile:					
a) Sterilization method is stated for each component (including dose for radiation sterilization).	X				
b) A description of method to validate the sterilization parameters is provided for each proposed sterilization method (e.g., half-cycle method and full citation of FDA-recognized standard, including date).	X				
c) For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant residuals remaining on the device and sterilant residual limits.			X		
d) Sterility Assurance Level (SAL) is stated.	X				
e) Submission includes description of packaging.	X				
f) For products labeled "non-pyrogenic," a description of the method used to make the determination stated (e.g., limulus amebocyte lysate [LAL]).			X		
22) If the device, and/or accessory, and/or a component is reusable or end user sterilized or disinfected:					

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
a) Cleaning method is provided in labeling for each device, and/or accessory, and/or component.			X		
b) Disinfection method is provided in labeling for each device, and/or accessory, and/or component.			X		
c) Sterilization method is provided in labeling for each device and/or accessory, and/or component.	X				
d) Device types in this submission are listed in Appendix E of the FDA's guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling."			X		
i) If device types in this submission are included in Appendix E of the reprocessing guidance, the submission includes protocols and test reports for validating the reprocessing instructions.			X		
23) The device has a device-specific guidance document, special controls document, and/or requirement in a device-specific regulation regarding sterility and/or reprocessing that is applicable to the subject device.	X				
a) The submission addresses sterility and/or reprocessing recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria.			X		
b) The submission includes sterility and/or reprocessing information that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness.	X				
F. Shelf Life					
24) Proposed shelf life/expiration date stated **OR** Statement that shelf-life is not applicable because of low likelihood of time-dependent product degradation	X				
25) For a sterile device, submission includes summary of methods used to establish that device packaging will maintain a sterile barrier for the entirety of the proposed shelf life.	X				
26) Submission includes summary of methods used to establish that device performance is maintained for the entirety of the proposed shelf-life (e.g., mechanical properties, coating integrity, pH, osmolality, etc.). **OR** Statement why performance data is not needed to establish maintenance of device performance characteristics over the shelf-life period.	X				
G. Biocompatibility					
If an vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.					
Submission states that there: (one of the below must be checked)					

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
× Are direct or indirect patient-contacting components.					
Are no direct or indirect patient-contacting components.					
Information regarding patient contact status of the device is not provided (if this box checked, please also check one of the two boxes below).					
Patient contact information not needed for this device (e.g., software-only device)					
Patient contact information needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
27) Submission includes a list identifying each of patient-contacting device component (e.g., implant, delivery catheter) and associated materials of construction for each component, including identification of color additives, if present.	×				
28) Submission identifies contact classification (e.g., surface-contacting, less then 24 hour duration) for each patient-contacting device component (e.g., implant, delivery catheter)	×				
29) Biocompatibility assessment of patient-contacting components Submission includes: Test protocol (including identification and description of test article), methods, pass/fail criteria, and results provided for each completed test. **OR** A statement that biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate).	×				
H. Software					
Submission states that the device: (one of the below must be checked)					
Does contain software/firmware					
× Does not contain software/firmware					
Information on whether device contains software/firmware is not provided. (If this box is checked, please also check one of the two boxes below.)					
Software/firmware information not needed for this device (e.g., surgical suture, condom)					
Software/firmware information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
I. Electrical Safety and EMC					
Electrical Safety Submission states that the device: (one of the below must be checked)					
Does require electrical safety evaluation					
× Does not require electrical safety evaluation					
Information on whether device requires electrical safety evaluation is not provided. (If this box is checked, please also check one of the two boxes below.)					
Electrical safety information not needed for this device (e.g., surgical suture, condom)					

Electrical safety information not needed for this device (e.g., surgical suture, condom)

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
Electrical safety information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
EMC Submission states that the device: (one of the below must be checked)					
Does require EMC evaluation					
X Does not require EMC evaluation					
Information on whether device requires EMC evaluation is not provided. (If this box is checked, please also check one of the two boxes below.)					
EMC information not needed for this device (e.g., surgical suture, condom)					
EMC information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
J. Performance Data - General					
If an in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from checklist if "N/A" is selected. Performance data criteria relating to IVD devices is addressed in Section K.					
34) Full test report is provided for each completed test. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre-defined pass/fail criteria, results summary, conclusions.	X				
a) Submission includes an explanation of how the data generated from each test report supports a finding of substantial equivalence (e.g., comparison to predicate device testing, dimensional analysis, etc.).	X				
35) The device has a device-specific guidance document, special controls document, and/ or requirements in a device-specific regulation regarding performance data that is applicable to the subject device.	X				
a) The submission addresses performance data recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria.			X		
b) The submission includes performance data that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness.	X				
36) If literature is referenced in the submission, submission includes:			X		
37) For each completed animal study, the submission provides the following:			X		
K. Performance Characteristics - In Vitro Diagnostic Devices Only **(Also see 21 CFR 809.10(b)(12))**					

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
Submission states that the device: (one of the below must be checked)					
	is an in vitro diagnostic device.				
X	is not an in vitro diagnostic device.				
If "is not" is selected, the performance data-related criteria below are omitted from the checklist.					

Decision: ◉ Accept ○ Refuse to Accept

If Accept, notify applicant.

If Refuse to Accept, notify applicant electronically and include a copy of this checklist.

Digital Signature Concurrence Table	
Reviewer Sign-Off	Andrew I. Steen -S 2015.11.18 12:10:22 -05'00'
Branch Chief Sign-Off (digital signature optional)*	
Division Sign-Off (digital signature optional)*	

* Branch and Division review of checklist and concurrence with decision required. Branch and Division digital signature optional.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

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

K153064
Blue Sky Bio, LLC
Device Trade Name: Blue Sky Bio Zygomatic Impant System
Contact Name: Kevin Thomas

DEFICIENCY LIST

(b)(4)

(b)(4)

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DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

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

April 29, 2016

Blue Sky Bio, LLC
c/o Kevin A. Thomas, Ph.D.
Regulatory Affairs
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130

Re: K153064
Trade/Device Name: Blue Sky Bio Zygomatic Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: March 31, 2016
Received: March 31, 2016

Dear Dr. Thomas:

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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 Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K153064

Device Name

Blue Sky Bio Zygomatic Implant System

Indications for Use *(Describe)*

Blue Sky Bio Zygomatic Implant System is indicated for surgical installation in the zygoma region, in cases of severe jaw resorption, in order to restore patient esthetics and chewing function. Blue Sky Bio zygomatic implants are recommended for the posterior (pre-molar/molar) region, one implant on each side, with at least two standard dental implants in the anterior region to support a fixed restoration. Blue Sky Bio zygomatic implants may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Blue Sky Bio, LLC

Blue Sky Bio Zygomatic Implant System

April 28, 2016

ADMINISTRATIVE INFORMATION

Manufacturer Name	Blue Sky Bio, LLC 888 E Belvidere Road, Suite 212 Grayslake, IL 60030 Telephone +1 718-376-0422 Fax +1 888-234-3685
Official Contact	Michele Vovolka Vice President of RA/QA
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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	Blue Sky Bio Zygomatic Implant System
Common Name	Endosseous dental implant Endosseous dental implant abutment
Classification Regulations	21 CFR 872.3640
Product Code	DZE NHA
Classification Panel	Dental Products Panel
Reviewing Branch	Dental Devices Branch

PREDICATE DEVICE INFORMATION

Primary predicate device:
K141777, Neodent Implant System, JJGC Indústria e Comércio de Materiais Dentários SA

Reference predicate devices:
K102034, Blue Sky Bio Dental Implant System, Blue Sky Bio, LLC
K060957, Blue Sky Bio Dental Implant System, Blue Sky Bio, LLC
K093562, Zygomatic Implant System, Southern Implants, Inc.

INTENDED USE

Blue Sky Bio Zygomatic Implant System is indicated for surgical installation in the zygoma region, in cases of severe jaw resorption, in order to restore patient esthetics and chewing function. Blue Sky Bio zygomatic implants are recommended for the posterior (pre-molar/molar) region, one implant on each side, with at least two standard dental implants in the anterior region to support a fixed restoration. Blue Sky Bio zygomatic implants may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.

DEVICE DESCRIPTION

Blue Sky Bio Zygomatic Implant System submission includes threaded root-form dental implants and mating abutments designed for placement into the zygomatic bone. The zygomatic implants are provided with an internal hexagon connection and a tapered internal hexagon interface for connection to the subject abutments. The internal hexagon connection implants are provided with a body diameter of 4.7 mm and platform diameters of 3.5 mm and 4.5 mm. The tapered internal hexagon connection implants are provided with a body diameter of 4.3 mm and a narrow platform (NP) connection, and with a body diameter of 5.0 mm with a regular platform (RP) connection. All implants are provided in multiple overall threaded lengths ranging from 35 mm to 55 mm. This submission includes mating abutments with platform diameters of 3.5, 4.3, and 4.5 mm, and each abutment diameter is provided with 17° and 30° of angulation. All subject device abutments are for support of screw-retained overdenture prosthetic restorations. The abutment screws compatible with the subject device abutments were cleared in K060957 and K102034. The subject device zygomatic implants and abutments are made of titanium alloy conforming to ASTM F136 *Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401).* The previously cleared abutment screws also are made of material conforming to ASTM F136.

PERFORMANCE DATA

Non-clinical data submitted, referenced, or relied upon to demonstrate substantial equivalence include: biocompatibility (referenced from K102034 and K060957), engineering analysis, dimensional analysis, and dynamic compression-bending testing of the Taper Hex 4.3 mm body diameter implant with the NP platform according to ISO 14801 *Dentistry – Implants – Dynamic fatigue test for endosseous dental implants.* No clinical data were included in this submission.

EQUIVALENCE TO MARKETED DEVICE

Blue Sky Bio, LLC submits the following information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, the subject device is substantially equivalent in indications and design principles to the following legally marketed predicate devices:

K141777, Neodent Implant System, JJGC Indústria e Comércio de Materiais Dentários SA;

K102034, Blue Sky Bio Dental Implant System, Blue Sky Bio, LLC;

K060957, Blue Sky Bio Dental Implant System, Blue Sky Bio, LLC; and

K093562, Zygomatic Implant System, Southern Implants, Inc.

A comparison of the technological characteristics of the subject device and the primary predicate device K141777 is provided in the following table.

	Subject Device	**Primary Predicate Device**
Comparison	Blue Sky Bio, LLC Blue Sky Bio Zygomatic Implant System K153064	JJGC Indústria e Comércio de Materiais Dentários SA Neodent Implant System K141777
Indications for Use	Blue Sky Bio Zygomatic Implant System is indicated for surgical installation in the zygoma region, in cases of severe jaw resorption, in order to restore patient esthetics and chewing function. Blue Sky Bio zygomatic implants are recommended for the posterior (pre-molar/molar) region, one implant on each side, with at least two standard dental implants in the anterior region to support a fixed restoration. Blue Sky Bio zygomatic implants may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.	Zygomatic Implants are indicated for surgical installation in the zygoma region, in cases of severe jaw resorption, in order to restore patient esthetics and chewing function. Zygomatic Implants are recommended for the posterior (pre-molar/molar) region, one implant on each side, with at least two standard dental implants in the anterior region to support a fixed restoration. Zygomatic Implants may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.
Implants		
Design	Threaded root-form implant to be used with mating abutments	Threaded root-form implant to be used with mating abutments
Implant body Ø and Platform Ø	Internal hex connection Implant body Ø: 4.7 mm Abutment platform Ø: 3.5 mm, 4.5 mm (implant body tapers at apical portion)	External hex and Morse taper Implant body Ø: 4.4 mm tapering to 3.9 mm Platform Ø: 4.1 mm
	Tapered internal hex connection Implant body Ø: 4.3 mm with NP 3.5 mm abutment platform Implant body Ø: 5.0 mm with RP 4.3 mm abutment platform (implant body tapers at apical portion)	
Implant Lengths	All implants: 35, 37.5, 40, 42.5, 45, 47.5, 50, 52.5, 55 mm	External hex: 30, 35, 40, 45, 47.5, 50, 52.5 mm Morse taper: 30, 35, 40, 42.5, 45, 47.5, 50, 52.5 mm
Implant-Abutment Interface		
Type	Internal hex with 12° taper Internal hex with 45° bevel	External hex Morse taper
Implant body-abutment connection angle	n/a	45°
Abutments		
Platform Diameter	Internal hex connection: 3.5 mm, 4.5 mm Tapered internal hex connection: 4.3 mm	4.1 mm
Abutment Angle	17°, 30°	0° (straight)

	Subject Device	Primary Predicate Device
Comparison	Blue Sky Bio, LLC Blue Sky Bio Zygomatic Implant System K153064	JJGC Indústria e Comércio de Materiais Dentários SA Neodent Implant System K141777
Materials		
Implants	Ti-6Al-4V	F67 unalloyed titanium, grade 4
Implant Surface	Grit blasted and acid etched	Machined
Abutments	Ti-6Al-4V	F136 Ti-6Al-4V ELI
Abutment Screws	Ti-6Al-4V	External hex: F136 Ti-6Al-4V ELI

The subject device and the primary predicate K141777 have substantially equivalent indications for use, including restoration of patient esthetics and chewing function, and immediate loading when used with standard dental implants placed in the anterior region to support a fixed restoration. The implants of the subject device and the predicate device K141777 have similar designs and dimensions, including lengths appropriate for zygomatic placement.

The subject zygomatic implants are very similar in design to endosseous dental implants from Blue Sky Bio cleared in K102034 and K060957, except for a slight change in the endosseous thread and the longer lengths appropriate for zygomatic placement. The subject zygomatic implants are provided in a range of implant body diameters (maximum endosseous thread diameters) of 4.3 mm to 5.0 mm, the same as the predicate implants cleared in K102034 and K060957. The smaller subject device implant body (4.3 mm diameter) as compared to the primary predicate K141777 (4.4 mm diameter) is supported by the reference predicate K093562 (4.05 mm body diameter), and by and dynamic compression-bending testing according to ISO 14801.

The subject device implants are provided in the same range of overall lengths as the primary predicate K141777 (35 mm to 52.5 mm), and the subject device 55 mm length implant is supported by the reference predicate K093562.

This submission includes abutments with an internal hexagon and tapered internal hexagon interfaces for connection to the subject zygomatic implants. The subject device abutments are provided with platform diameters of 3.5, 4.3, and 4.5 mm, and angulation of 17° or 30°. The subject device abutments are substantially equivalent to the abutments cleared in K102034 and K060957 in terms of implant-abutment connections, platform diameters, angulation, and materials. The subject abutments are to be used with compatible abutment screws cleared in K102034 and K060957.

Differences between the subject device and the primary predicate K141777 include the location of angulation correction (subject device includes abutments with angulation, versus K141777 implant designs included angulation at the abutment-implant connection), and the amount of angulation (subject device 17° or 30°, versus K141777 only 45°). These differences between the subject device and the primary predicate are supported by dynamic compression-bending testing according to ISO 14801. Dynamic testing of worst case subject device constructs consisting of the smallest diameter implant (Taper Hex 4.3 mm body diameter) and largest angulation (30°)

demonstrated fatigue performance substantially equivalent to that of the primary predicate K141777.

The subject device implants and abutments are made of titanium alloy conforming to ASTM F136 *Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)*, the same as these components cleared in K102034 and K060957. The endosseous surface finish of the subject device implants is the same as the predicate implants cleared in K102034 and K060957.

The subject device implants have similar packaging and are sterilized using the same materials and processes as described in K102034 and K060957. The subject device abutments are provided nonsterile in similar packaging and are to be sterilized using the same processes as described in K102034 and K060957.

CONCLUSION

The subject device and the predicate devices have the same intended use, have similar technological characteristics, and are made of similar materials. The subject device and predicate devices encompass the same range of physical dimensions, including diameter and length of the implants, and the diameter and angulation of the abutments. The subject and predicate devices are packaged in similar materials and sterilized using similar methods.

The data included in this submission demonstrate substantial equivalence to the predicate devices listed above.