K113246

510(k) Summary

[as required by 807.92(c)]

JAN 16 2013

Sponsor/Applicant

NIBEC Co., Ltd.

Iwol electricity-electronic Agro-industrial Complex, 1127, Sinwol-ri,

Iwol-myeon, Jincheon-gun, Chungcheongbuk-do, Korea

Phone : 82-10-2889-8590

Fax : 82-2-744-8732

Contact : Dr. Park, Yoon-Jeong

Date Prepared : JANUARY 07, 2013

Device Name and Identification

Proprietary Name : OCS-B™

Common / Usual Name : Bone Mineral Matrix

Anorganic Bovine Bone Grafting Material

Classification Name : Bone Grafting Material

Animal Source Dental Bone Grafting Material

Predicate Device

Bio-Oss® bone grafting material (K871773, K952617, K970321, K033815)

Manufactured by :

Geistlich Pharma AG

Bahnhofstrasse 40

CH-6110 Wolhusen

Switzerland

Device Category/Class

Device Class : Class II

Regulation Number : 21 C.F.R. 872.3930

Product Code : NPM

Indication for use

OCS-B™ cancellous and cortical granules are recommended for:

- Augmentation or reconstructive treatment of the alveolar ridge.
- Filling of infrabony periodontal defects.
- Filling of defects after root resection, apicoectomy, and cystectomy
- Filling of extraction sockets to enhance preservation of the alveolar ridge
- Elevation of maxillary sinus floor
- Filling of periodontal defects in conjunction with products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR)
- Filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration (GBR)

Device Description

OCS-B™ is a sterile, porous bone mineral matrix produced by the removal of organic compounds from bovine bone. It is supplied as cancellous (spongiosa) or cortical granules in a single use container, packaged in a secondary thermoform blister, and sterilized by γ-irradiation.

Basis for Substantial Equivalence

OCS-B™ and Bio-Oss® have a similar physical and chemical structure. Both are porous, biocompatible bone grafts that facilitate the formation and mineralization of new bone by the

osteoblast. As both products have same source of bone (bovine source) and similar process for removal of organic compounds, the product is substantially equivalent to Bio-Oss®.

The following table summarizes the basis for the Sponsor's substantial equivalence determination :

Table 1 Substantial Equivalence Comparison

ITEM	OCS-B™	Bio-Oss®
Intended Use	Used as an adjective therapy in restoring bony defects	Used as an adjective therapy in restoring bony defects
Target population	Human Oral, Periodontal	Human Oral, Periodontal
Dosage form	Granules contained in single use container	Granules contained in single use container
Granule sizes	0.2mm to 1.0mm or 1.0mm to 2.0 mm granules	0.25mm to 1.0mm or 1.0mm to 2.0 mm granules
Material	Anorganic derived osteoconductive hydroxyapatite bone mineral	Anorganic derived osteoconductive hydroxyapatite bone mineral
Source bone	Bovine bone	Bovine bone
Physical Morphology	Trabecular, interconnecting macro and micro pores	Trabecular, interconnecting macro and micro pores
Biocompatibility	Biocompatible, as demonstrated by : - Genotoxicity testing *(In vitro, In vivo)* - Intracutaneous reactivity testing - Maximization and sensitization testing - Pyrogen testing - Acute systemic toxicity testing - Cytotoxicity testing - Implantation testing - Preclinical safety and efficacy testing - Clinical case studies	Biocompatible (as demonstrated in published literature)

Performance	Bone formation	Bone formation
Compatibility w/other devices	Can be used with GTR membrane	Can be used with GTR membrane
Sterilization Process	Sterile by Gamma irradiation	Sterile by Gamma irradiation
Chemical Composition	Similar to Bio-Oss® based on chemical analysis, XRD, FT-IR and ICP analysis	Similar to OCS-B™ based on chemical analysis, XRD, FT-IR and ICP analysis
Anatomical sites	Oral, Periodontal	Oral, Periodontal
Non-pyrogenic	Yes	Yes
Shelf life	3 years	Determined by Manufacturer
Risk	Non-risk, as demonstrated by : - TSE inactivation Process Validation - Virus Clearance study - Analysis of residual solvent - Risk analysis - Cleaning Validation	-

Brief Summary of Data Submitted

The Sponsor evaluated the performance characteristics of OCS-B™ and Bio-Oss® with a thorough chemical and physical characterization. The physical and chemical characteristics of the products were found to be comparable. Further, in several animal studies, both products were found to grow new bone and be subsequently resorbed at similar rates. Finally, in a clinical case series, use of OCS-B™ resulted in defect healing and formation of new bone of sufficient quality to obtain dental implant placement. The submission includes a summary of seven individual case studies of OCS-B™. The patients were treated for intra-bony periodontal defects. For each case study, the report includes baseline radiographs, radiographs at various time point, and core biopsy for histological evaluation. Histological and radiographic images demonstrate new bone growth.

OCS-B™ was the subject of the full range of biocompatibility tests recommended in the FDA's "Class II. Special Controls Guidance Document : Dental Bone Grafting Devices" and in accordance with ISO 10993. Organic material has been removed from the product, and product specifications have been established to limit protein content. Throughout the risk analysis for each production step, for example, cleaning validation, the removal of organic solvent, the risk control was conducted during the manufacturing process. In addition, the

TSE inactivation validation as well as virus inactivation study result was conducted. Further, the product is sterilized to achieve a sterility assurance level SAL 1 x 10^{-6}.

Based on the information presented herein, it has been demonstrated that OCS-B™ is substantially equivalent to Bio-Oss®.

Conclusion

The OCS-B™ presents the same types of potential risks to consumers as the predicate device Bio-Oss®, and has controlled these risks in a similar manner. And biocompatibility tests and compatibility test show that the device meets the requirements of those standards. Literatures and post market experience show that the device is substantially equivalent. Comparison with the predicate device shows that the device has similar specification and performance.

Therefore, it is concluded that OCS-B™ are substantially equivalent to the predicate device.

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

January 16, 2013

Nibec Company, Limited
C/O Mr. Daniel Nam
General Manager
Pats Corporation
4568 West 1st Street, Suite 104
LOS ANGELES CA 90004

Re: K113246
Trade/Device Name: OCS-B™
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: NPM
Dated: January 7, 2013
Received: January 14, 2013

Dear Mr. Nam:

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,

Kwame O. Ulmer

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113246

Device Name: OCS-B™

Indications for Use:

OCS-B™ cancellous and cortical granules are recommended for:

- Augmentation or reconstructive treatment of the alveolar ridge.
- Filling of infrabony periodontal defects.
- Filling of defects after root resection, apicoectomy, and cystectomy
- Filling of extraction sockets to enhance preservation of the alveolar ridge
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- Filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration (GBR)

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner DDS, MA 2013.01.15 15:02:04 -05'00'

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

510(k) Number: K113246

DEPARTMENT OF HEALTH & 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

November 03, 2011

NIBEC COMPANY, LIMITED
C/O PATS CORP.
1415-1441 GARDENA AVE.
GLENDALE, CALIFORNIA 91204
ATTN: DANIEL NAM

510k Number: K113246
Received: 11/2/2011
Product: OCS-B

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. 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.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm
for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007" http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html. In addition, the 510(k) Program Video is now available for viewing on line at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm .

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041 , or at their internet address http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff

DEPARTMENT OF
HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

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Sincerely yours,

Kwame O. Ulmer

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Concurrence & Template History Page
[THIS PAGE IS INCLUDED IN IMAGE COPY ONLY]

Full Submission Number: K113246

For Office of Compliance Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=318

For Office of Surveillance and Biometrics Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=423

Digital Signature Concurrence Table	
Reviewer Sign-Off	Lauren M. Giles 2013.01.16 14:27:43 -05'00'
Branch Chief Sign-Off	Susan Runner DDS, MA 2013.01.16 14:24:44 -05'00'
Division Sign-Off	Kwame O. Ulmer 2013.01.16 14:11:06 -05'00'

Template Name: K1(A) – SE after 1996

Template History:

Date of Update	By	Description of Update
7/27/09	Brandi Stuart	Added Updates to Boiler Table
8/7/09	Brandi Stuart	Updated HFZ Table
1/11/10	Diane Garcia	Liability/Warranty sentence added at bottom of 1st page
10/4/11	M. McCabe Janicki	Removed IFU sheet and placed in Forms
9/25/12	Edwena Jones	Added digital signature format
12/12/12	M. McCabe Janicki	Added an extra line between letter signature block and the word "Enclosure". Also, added a missing digit in 4-digit extension on letterhead zip code: "002" should be "0002".

Indications for Use

510(k) Number (if known): K113246

Device Name: OCS-B™

Indications for Use:

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- Augmentation or reconstructive treatment of the alveolar ridge.
- Filling of infrabony periodontal defects.
- Filling of defects after root resection, apicoectomy, and cystectomy
- Filling of extraction sockets to enhance preservation of the alveolar ridge
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- Filling of periodontal defects in conjunction with products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR)
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Prescription Use ___X___ AND/OR Over-The-Counter Use _____ (Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner DDS, MA 2013.01.15 15:02:04 -05'00'

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

510(k) Number: K113246

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

January 14, 2013

NIBEC COMPANY, LIMITED
C/O PATS CORP.
4568 W. 1ST STREET
SUITE 104
LOS ANGELES, CALIFORNIA 90004
ATTN: DANIEL NAM

510k Number: K113246

Product: OCS-B

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

94

Mcdonald, Lisa *

From: Microsoft Outlook
To: (b) (6)
Sent: Monday, January 14, 2013 2:41 PM
Subject: Relayed: K113246/S004 AI Letter

Delivery to these recipients or groups is complete, but no delivery notification was sent by the destination server:

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Subject: K113246/S004 AI Letter

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Mcdonald, Lisa *

From: Microsoft Outlook
To: DCCLetters
Sent: Monday, January 14, 2013 2:41 PM
Subject: Delivered: K113246/S004 AI Letter

Your message has been delivered to the following recipients:

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Subject: K113246/S004 AI Letter

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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

eCopy Hold Letter

January 10, 2013

Daniel Nam, Representative
Nibec Company, Limited
C/O Pats Corp.
4568 W. 1st Street, Suite 104
Los Angeles, CA 90004
United States

Dear Daniel Nam:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) acknowledges receipt of your submission. This submission has been assigned the following unique document control number. Failure to reference this assigned number in future correspondence may result in processing delays.

510(k) Number: K113246/S004
Device: Ocs-B
Dated: 07-JAN-2013
Received: 10-JAN-2013

The Federal Food, Drug, and Cosmetic Act (the Act), as amended by section 1136 of the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to require an electronic copy (eCopy) for certain types of submissions. An eCopy is an exact duplicate of a paper submission, created and submitted on a CD, DVD, or other electronic media, accompanied by a signed cover letter and the complete original paper submission. This authorization applies to the original, amendments, supplements, and reports, as applicable, for your submission type.

You have received this letter because you have either not provided an eCopy or you provided an eCopy that failed the loading process because it did not conform to the technical standards. If you provided an eCopy that failed the loading process, then please see the attached document that identifies all reasons for the failure that need to be addressed.

Please write the specific submission number above AND "Replacement eCopy" directly on the CD (or other media) and send that with your revised cover letter to the CDRH Document Control Center (DCC) at the address below.

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

When your Replacement eCopy has been received and been verified as a valid eCopy, review of this submission will start as of that date. If a valid Replacement eCopy has not been received within 180 days, your submission will be deleted from the system.

97

For more information about FDA's new 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. In addition, we strongly encourage you to visit FDA's eSubmitter website at http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm221506.htm in order to develop an eCopy in accordance with the new technical standards prior to sending it to FDA.

If you have any questions concerning this letter, please contact Ms. Samie Allen at (301) 796-6055 or at samie.allen@fda.hhs.gov.

Sincerely yours,

Samie Allen
Policy Analyst
Office of Device Evaluation
Center for Devices and Radiological Health

Mcdonald, Lisa *

From: Microsoft Outlook
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Mcdonald, Lisa *

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Subject: K113246/S001 eCopy Hold Letter

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PATS corp.
CERTIFICATION BUSINESS

4568 W. 1st Street, Suite 104
Los Angeles, California, 90004
email: pats0433@yahoo.com
Phone: 213-626-1544 FAX: 213-626-1548

May 4, 2012
Document Mail Center
Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring. MD20993-0002

RE: Request for extension of the revised submission (K113246)

Reference: K113246
Product: OCS-B
Submitter: NIBEC Co., Ltd.
Applicant: PATS CORP
Manufacturer: NIBEC Co., Ltd.

Dear Officer Lauren Giles,

We appreciate your comments on our 510K submission. We have received your letter of requirements regarding the product with the 510K number, **K113246** as shown above. All of your comments are being seriously considered and being reflected in our revised submission. However, the issue of test report to solve several deficiencies you're raised has been delayed than our previous schedule. To this regard, we would like to extend the submission deadline as June 11, 2012.

If you have any question, please feel free to contact me. Thanks.

Best regards,

Daniel Nam (General Manager)
Authorized Agent of 510K Applicant

DEPARTMENT OF HEALTH & 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

January 04, 2012

NIBEC COMPANY, LIMITED
C/O PATS CORP.
4568 W. 1ST STREET
SUITE 104
LOS ANGELES, CALIFORNIA 90004
ATTN: DANIEL NAM

510k Number: K113246

Product: OCS-B

Extended Until: 01/16/2012

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information (AI) is not received by the "Extended Until" date shown above, your premarket notification will be considered withdrawn (21 CFR 807.87(l)). If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

101

Nichols, Karl *

From: Microsoft Outlook
To: (b) (6)
Sent: Wednesday, January 04, 2012 4:24 PM
Subject: Relayed: K113246- Extension Letter

Delivery to these recipients or distribution lists is complete, but delivery notification was not sent by the destination:

(b) (6)

Subject: K113246- Extension Letter

Sent by Microsoft Exchange Server 2007

102

PATS corp.
CERTIFICATION BUSINESS

4568 W. 1st Street, Suite 104
Los Angeles, CA 90004
e-Mail: pats0433@yahoo.com
Phone: 213-626-1544 FAX: 213-626-1548

Dec 14, 2011
Document Mail Center
Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring. MD20993-0002

RE: Request for extension of the time

Reference: K113246
Product: OCS-B
Submitter: NIBEC CO LTD.
Applicant: PATS CORP
Manufacturer: NIBEC CO LTD.

Dear Officer

We got the letter of your requirements regarding the product (**k113246**) above.
Due date will be delayed to submit your requirements.
Please understand about it.

Hence, I would like to ask for time extension on Jan 15th 2012
Also the address of US agent is changed from 1435 Gardena Ave., Unit 13 Glendale, CA 91204 to 4568 W. 1st Street, Suite 104 Los Angeles, CA 90004.
Please send the mails to the new address when needed.

Thank you.

Very truly yours,

Mr. Daniel Nam / General Manager
Authorized Agent for 510K Applicant.

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DEPARTMENT OF HEALTH & 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

December 02, 2011

NIBEC COMPANY, LIMITED
C/O PATS CORP.
1415-1441 GARDENA AVE.
GLENDALE, CALIFORNIA 91204
ATTN: DANIEL NAM

510k Number: K113246
Product: OCS-B
On Hold As of 12/1/2011

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

Nichols, Karl *

From: Microsoft Exchange
To: (b) (6)
Sent: Friday, December 02, 2011 3:58 PM
Subject: Relayed: K113246 Hold Letter

Delivery to these recipients or distribution lists is complete, but delivery notification was not sent by the destination:

(b) (6)

Subject: K113246 Hold Letter

Sent by Microsoft Exchange Server 2007

106

DEPARTMENT OF HEALTH & 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

November 03, 2011

NIBEC COMPANY, LIMITED
C/O PATS CORP.
1415-1441 GARDENA AVE.
GLENDALE, CALIFORNIA 91204
ATTN: DANIEL NAM

510k Number: K113246
Received: 11/2/2011
Product: OCS-B

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. 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.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm
for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007" http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissio ·/PremarketNotification510k/ucm134034.htm. According to the draft guidance, 510(k) submissions that do not ·ontain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html. In addition, the 510(k) Program Video is now available for viewing on line at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm .

'lease ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per .1 CFR 807.93, it meets the content and format regulatory requirements.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041 , or at their internet address http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff

115

Benjamin, Mark D*

From: Microsoft Exchange
[redacted]
Sent: Thursday, November 03, 2011 11:01 AM
Subject: Relayed: Export.jsp

Delivery to these recipients or distribution lists is complete, but delivery notification was not sent by the destination:

[redacted]

Subject: Export.jsp

Sent by Microsoft Exchange Server 2007

116

De / DAGID K113246

PATS corp. CERTIFICATION BUSINESS

1415-1441 Gardena Ave,
Glendale California 91204 USA
e-Mail: pats0433@yahoo.com
Phone: 213-626-1544 FAX: 213-626-1548

Aug 20, 2011
Document Mail Center
Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring. MD20993-0002

FDA CDRH DMC
NOV 0 2 2011
Received K9

Attention: Document Mail Clerk

Re: Cover Letter
Traditional 510K Notifications for Bone grafting material
Product:OCS-B

- Pursuant to the requirements of Section 510K of the Food, Drug and Cosmetic Act, notification is hereby made of the intention of the **Submitter**, **<NIBEC Co., Ltd. >**, < Iwol electricity-electronic Agro-industrial Complex, 1127, Sinwol-ri, Iwol-myeon, Jincheon-gun, Chungcheongbuk-do, Korea >. The **Applicant of this 510K submission is. <Pats corp>**. The **Manufacturer is < NIBEC Co., Ltd. >**.

The purpose of this notification is to establish the equivalency of the product to other legally marketed devices, and provide documentation demonstrating such equivalency.

The following information is being provided in conformance with 21 CFR 807.87.

1. **Classification Name:** Bone Filling Material
2. **Common / Usual Name**: An organic Bovine Bone Filling Material
3. **Proprietary Name:** OCS-B
4. **Establishment Registration:** Pending
5. **Classification / Product Code:** Unclassified / NPM
6. **Labeling, User Manual, Advertising Literature:** See Label and Package
7. **Intended Use:**
   Intended for use in dental surgery.
   The products may be used in surgical procedures such as:
   * Augmentation or reconstructive treatment of alveolar ridge
   * Filling of periodontal defects
   * Filling of defects after root resection, apicocectomy, and cystectomy
   * Filling of extraction sockets to enhance preservation of the alveolar ridge
   * Elevation of maxillary sinus floor
     * Filling of periodontal defects in conjunction with products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR)
   * Filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration
8. **Substantial Equivalence**

-Predicate Device
SE Number: K033815
Product name: BIO-OSS®, BIO-OSS®) Blocks, BIO-OSS® Collagen
Company: Geistlich Pharma Ag.
The subject device and predicate devices are substantially equivalent. All have the same intended use.....

It is our intent that the marking of this device is considered confidential information and is to be treated as such by the FDA.

PATS corp.
CERTIFICATION BUSINESS

1415-1441 Gardena Ave,
Glendale California 91204 USA
e-Mail: pats0433@yahoo.com
Phone: 213-626-1544 FAX: 213-626-1548

We would appreciate your earliest attention to this 510K submission. If you have any question or comments, please feel free to contact me at any time.

Very truly yours,

/ Daniel Nam
Authorized Agent for
NIBEC Co., Ltd
and 510K Applicant.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER
   NIBEC Co., Ltd.

2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
   09/02/2011

3. ADDRESS *(Number, Street, State, and ZIP Code)*
   Iwol electricity-electronic Agro-industrial Complex, 1127, Sinwol-ri, Iwol-myeon, Jincheon-gun, Chungcheongbuk-do, Korea

4. TELEPHONE AND FAX NUMBER *(Include Area Code)*
   (Tel.) 82 43-532-7458
   (Fax) 82 43-532-7458

PRODUCT INFORMATION

5. **FOR DRUGS/BIOLOGICS:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
   FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
   (Attach extra pages as necessary)

Device Classification Name : Esophageal Prosthesis

Device Name: An organic Bovine Bone Filling Material

Product Code : NPM

Trade name: OCS-B

21 CFR 872.3930

Device Class : Unclassified

APPLICATION / SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER *(If number previously assigned)*

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

CERTIFICATION STATEMENT / INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES *(See instructions for additional information and explanation)*

☒ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

☐ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

☐ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/ SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES *(Attach extra pages as necessary)*

NCT Number(s):

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are proh bited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.
Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign)

12. NAME AND TITLE OF THE PERON WHO SIGNED IN NO. 11
   (Name) Daniel Nam
   (Title) General Manager

13. ADDRESS *(Number, Street, State, and ZIP Code) (of person identified in No. 11 and 12)*
   1415-1441 Gardena Ave.,Glendale, CA 91204

14. TELEPHONE AND FAX NUMBER *(Include Area Code)*
   (Tel.) 213-626-1544
   (Fax) 213-626-1548

15. DATE OF CERTIFICATION
   09/02/2011

PSC Graphics (301) 443-1090 EF

Instructions for Completion of Form FDA 3674

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))
Form 3674 must accompany an application/submission, including amendments, supplements, and resubmissions, submitted under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.

1. **Name of Sponsor/Applicant/Submitter -** This is the name of the sponsor/applicant/submitter of the drug/biologic/device application/ submission which the certification accompanies. The name must be identical to that listed on the application/submission.

2. **Date -** This is the date of the application/submission which the certification accompanies.

3. **& 4. -** Provide complete address, telephone number and fax number of the sponsor/applicant/submitter.

5. **Product Information - For Drugs/Biologics:** Provide the established, proprietary name, and/or chemical/biochemical/blood product/ cellular/gene therapy name(s) for the product covered by the application/submission. Include all available names by which the product is known. **For Devices:** Provide the common or usual name, classification, trade or proprietary or model name(s), and/or model number(s). Include all available names/model numbers by which the product is known.

6. **Type of Application/Submission -** Identify the type of application/submission which the certification accompanies by checking the appropriate box. If the name of the type of application/submission is not identified, check the box labeled "Other."

7. **IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/Other Number -** If FDA has previously assigned a number associated with the application/ submission which this certification accompanies, list that number in this field. For example, if the application/submission accompanied by this certification is an IND protocol amendment and the IND number has already been issued by FDA, that number should be provided in this field.

8. **Serial Number -** In some instances a sequential serial number is assigned to the application. If there is such a serial number, provide it in this field.

9. **Certification -** This section contains three different check-off boxes.
   Box A should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply because no clinical trials are included, relied upon, or otherwise referred to, in the application/ submission which the certification accompanies.

   Box B should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply at the time of submission to any clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, at the time the application/submission is being made, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply to any of the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies.

   Box C should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do apply at the time of submission to some or all of the clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, at the time the application/ submission is being made, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, apply to one or more of the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies.

10. **National Clinical Trial (NCT) Numbers -** If you have checked Box C in number 9 (Certification), provide the NCT Number obtained from www.ClinicalTrials.gov for each clinical trial that is an "applicable clinical trial" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, and that is included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Type only the number, as NCT will be added automatically before number. Include any and all NCT numbers assigned to the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies. Multiple NCT numbers may be required for a particular certification, depending on the number of "applicable clinical trials" included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies.

11. **Signature of Sponsor/Applicant/Submitter or an Authorized Representative -** The person signing the certification must sign in this field.

12. **Name and Title of Person Who Signed in number 11. -** Include the name and title of the person who is signing the certification. If the person signing the certification is not the sponsor/applicant/submitter of the application/submission, he or she must be an authorized representative of the sponsor/applicant/submitter.

13. **& 14. -** Provide the full address, telephone and fax number of the person who is identified in number 11 and signs the certification in number 11.

15. Provide the date the certification is signed. This date may be different from the date provided in number 2.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 15 minutes and 45 minutes (depending on the type of application/submission) per response, including time for reviewing instructions. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to the applicable address below.

Food and Drug Administration
Center for Drug Evaluation and Research
Central Document Room
Form No. FDA 3674
5901-B Ammendale Road
Beltsville, MD 20705-1266

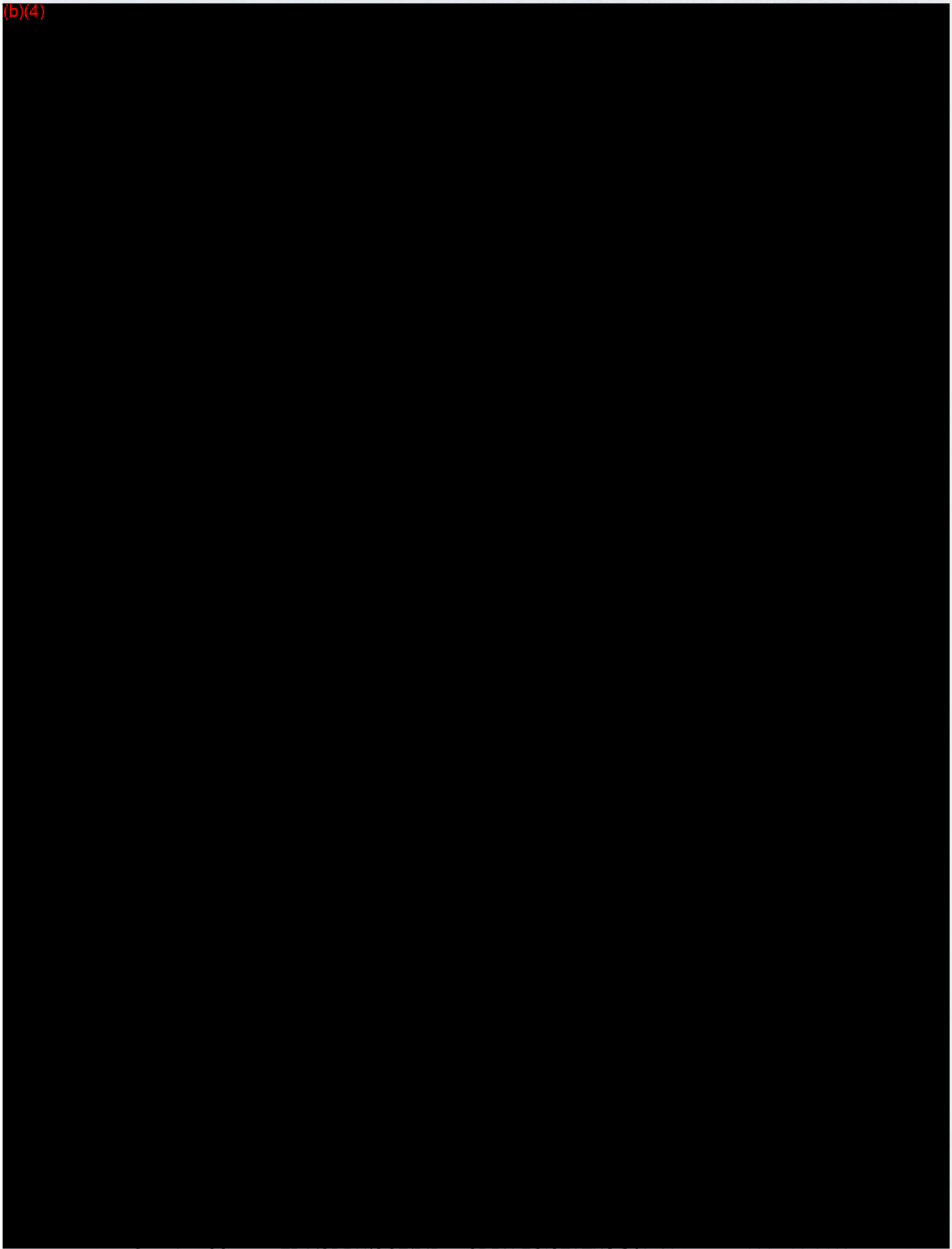
Food and Drug Administration
Center for Biologics Evaluation and Research
1401 Rockville Pike
Rockville, MD 20852-1448

Food and Drug Administration
Center for Devices and Radiological Health
Program Operations Staff (HFZ-403)
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 number.

FDA-3674 (1/08) (BACK)

(b)(4)



Form Approved OMB No. 0910-511. See Instructions for OMB Staten

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

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
NIBEC 1127 Shinwol-ri, Iwol-myeon CHINCHON 365824 KR	Chong Pyoung Chung 2.1 E-MAIL ADDRESS pats0433@yahoo.com 2.2 TELEPHONE NUMBER (include Area code) 82-435327458 2.3 FACSIMILE (FAX) NUMBER (Include Area code)
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)	

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/oc/mdufma

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)
[ ] Annual Fee for Periodic Reporting (APR)	[ ] Real-Time (PMA, PMR, PDP)
[ ] 30-Day Notice	[ ] 180-day (PMA, PMR, PDP)

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

[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA

[X] NO, I am not a small business

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

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

[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only

[ ] The sole purpose of the application is to support conditions of use for a pediatric population

[ ] 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, 1350 Piccard Drive, 4th Floor Rockville, MD 20850

[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) [redacted]

13-Oct-2011

"Close Window" Print Cover sheet

DEPARTMENT OF HEALTH AND HUMAN SERV CES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approva
OMB No. 9010-0120
Exp rat on Date: August 31, 2010.
See OMB Statement on page 5.

Date of Subm ss on	User Fee Payment ID Number	FDA Subm ss on Document Number *(if known)*
	(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 DE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre PMA Meeting
☐ Amendment	☐ 30 day Supplement		☐ Abbreviated (Complete section Page 5)	☐ Pre PDP Meeting
☐ Report	☐ 30 day Notice		☐ Additional nformation	☐ 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 nformation	☐ Additional nformation	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or c ted Standards n your subm ss on? ☐ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / nstitution Name	Establishment Registration Number *(if known)*		
NIBEC CO LTD			
Division Name *(if applicable)*	**Phone Number *(including area code)***		
	(82) 43-532-7458		
Street Address	**FAX Number *(including area code)***		
Iwol electricity-electronic Agro-industrial Complex, 1127, Sinwol-ri	( )		
City	**State / Province**	**Z P/Postal Code**	**Country**
J ncheon-gun,	Chungcheongbuk-do,	451-864	KOREA
Contact Name			
ChongpPyoung. Chung,			
Contact Title	**Contact E mail Address**		
Pres dent	pats0433@yahoo.com		

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

Company / nstitution Name			
PATS CORP			
Division Name *(if applicable)*	**Phone Number *(including area code)***		
	(213) 626-1544		
Street Address	**FAX Number *(including area code)***		
1415-1441 Gardena Ave	(213) 626-1548		
City	**State / Province**	**Z P/Postal Code**	**Country**
G enda e	CA	91204	USA
Contact Name			
Dan e Nam			
Contact Title	**Contact E mail Address**		
Representat ve	Pats0433@yahoo.com		

PSC Graphics (01 44 1090

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

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

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New ndication
- ☐ Addition of nstitution
- ☐ Expansion / Extension of Study
- ☐ RB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment DE
- ☐ Continued Access
- ☐ Change in
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ nformed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol Feasibility
  - ☐ Protocol Other
  - ☐ Sponsor
- ☐ Report submission
  - ☐ Current nvestigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final
- ☐ Repose to FDA Letter Concerning
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient nvestigator 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 ndications
- ☐ Change in Technology
- ☐ Other Reason *(specify):*

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	NPM	2		3		4	
5		6		7		8	

Summary of or statement concerning safety and effectiveness information

- [x] 510 (k) summary attached
- [ ] 510 (k) statement

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

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	k033815	1	BIO-OSS®, BIO-OSS®) Blocks,	1	Geistlich Pharma Ag
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

bone grafting material, animal source

	Trade or Proprietary or Model Name for This Device		Model Number
1	OCS-B	1	V a , Bow , Syr nge type
2		2	
3		3	
4		4	
5		5	

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

1	2	3	4	5	6
7	8	9	10	11	12

Data ncluded in Submission

- [ ] Laboratory Testing
- [x] Animal Trials
- [x] Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C F R Section *(if applicable)*	Device Class
NPM	872.3930	[ ] Class [ ] Class [ ] Class [x] Unclassified

Classification Panel

bone graft ng mater a , an ma source

ndications *(from labeling)*

Intended for use in dental surgery. The
products may be used in surgical procedures such as:* Augmentation or reconstructive treatment of alveolar ridge
* Filling of periodontal defects
* Filling of defects after root resection, apicocectomy, and cystectomy
* Filling of extraction sockets to enhance preservation of the alveolar ridge
* Elevation of maxillary sinus floor

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	Facility Establishment dentifer (FE) Number	☑ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler
Company / nstitution Name NIBEC CO LTD		Establishment Registration Number
Division Name *(if applicable)*		Phone Number *(including area code)* (82) 43-532-7458
Street Address Iwol electricity-electronic Agro-industrial Complex, 1127, Sinwol-ri, Iwol-m		FAX Number *(including area code)* ( )

City	State / Province	Z P/Postal Code	Country
Jincheon-gun,	Chungcheongbuk-do,		KOREA

Contact Name	Contact Title	Contact E mail Address
	Pres dent	

☐ Original ☐ Add ☐ Delete	Facility Establishment dentifer (FE) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler
Company / nstitution Name		Establishment Registration Number
Division Name *(if applicable)*		Phone Number *(including area code)* ( )
Street Address		FAX Number *(including area code)* ( )

City	State / Province	Z P/Postal Code	Country

Contact Name	Contact Title	Contact E mail Address

☐ Original ☐ Add ☐ Delete	Facility Establishment dentifer (FE) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler
Company / nstitution Name		Establishment Registration Number
Division Name *(if applicable)*		Phone Number *(including area code)* ( )
Street Address		FAX Number *(including area code)* ( )

City	State / Province	Z P/Postal Code	Country

Contact Name	Contact Title	Contact E mail Address

SECTION I — UTILIZATION OF STANDARDS

Note: Comp ete th s sect on f your app cat on or subm ss on c tes standards or nc udes a *Declaration of Conformity to a Recognized Standard* statement.

	Standards No.	Standards Organ zat on	Standards T t e	Vers on	Date
1	IEC 980		Graphical symbols for use in the labeling of medical devices	2003	
2	IEC1041		Information supplied by the manufacturer with medical devices	1998	
3	ISO 10993-1 : 2003		Biological evaluation of medical devices part 1 Evaluation and testing	2003	
4	ISO 10993 Series		Biological evaluation of medical devices		
5	ISO 10993-10 : 2002		Biological evaluation of medical devices part 10 Test for irritation and delayed-type hypersensit		
6	ISO 10993-11 : 2002		Biological evaluation of medical devices part 11 Test for systemic toxicity		
7	ISO 14971		Medical devices Application of risk management to medical devices	2007	

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information s est mated to average 0 5 hour per response, nc ud ng the t me for rev ew ng nstruct ons, search ng ex st ng data sources, gather ng and ma nta n ng the data needed, and comp et ng rev ew ng the co ect on of nformat on Send comments regard ng th s burden est mate or any other aspect of th s co ect on of nformat on, nc ud ng suggest ons for reduc ng th s burden to:

Food and D ug Adm n strat on
CDRH (HFZ 342)
9200 Corporate B vd
Rockv e, 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

PATS corp.
CERTIFICATION BUSINESS

1415-1441 Gardena Ave,
Glendale California 91204 USA
e-Mail: pats0433@yahoo.com
Phone: 213-626-1544 FAX: 213-626-1548

Oct 20, 2011
Document Mail Center
Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring. MD20993-0002

Attention: Document Mail Clerk

Reference: 510K Notifications
Product: OCS-B
Submitter: NIBEC Co., Ltd.
Applicant: PATS CORP
Manufacturer: NIBEC Co., Ltd.

In accordance with the attached letter, we hereby submit an original and two copies of a 510K premarket Notification. Please find enclosed the following.

Table of Contents

1. 510(k) Cover Letter
2. Truthful and Accurate Statement
3. Indication for Use
4. Safety and Effectiveness Statement
5. Screen Checklist
6. FDA Form 3674, Form 3654
7. Label and Package
8. User Manual
9. Product Description
10. Sterility Validation Report
11. Substantial Equivalence Report
12. Biocompatibility and Performance Test report
13. Risk Analysis Report
14. Clinical data
15. 510(k) Summary

Very truly yours,

/ Daniel Nam
Authorized Agent for
NIBEC Co., Ltd
and 510K Applicant.

1415-1441 Gardena Ave,
Glendale California 91204 USA
e-Mail: pats0433@yahoo.com
Phone: 213-626-1544 FAX: 213-626-1548

Aug 20, 2011
Document Mail Center
Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring. MD20993-0002

Attention: Document Mail Clerk

Re: Cover Letter
Traditional 510K Notifications for Bone grafting material
Product:OCS-B

- Pursuant to the requirements of Section 510K of the Food, Drug and Cosmetic Act, notification is hereby made of the intention of the **Submitter, <NIBEC Co., Ltd. >, <** Iwol electricity-electronic Agro-industrial Complex, 1127, Sinwol-ri, Iwol-myeon, Jincheon-gun, Chungcheongbuk-do, Korea **>**. The **Applicant of this 510K submission is. <Pats corp>**. The **Manufacturer is < NIBEC Co., Ltd. >**.

The purpose of this notification is to establish the equivalency of the product to other legally marketed devices, and provide documentation demonstrating such equivalency.

The following information is being provided in conformance with 21 CFR 807.87.

1. **Classification Name:** Bone Filling Material
2. **Common / Usual Name**: An organic Bovine Bone Filling Material
3. **Proprietary Name:** OCS-B
4. **Establishment Registration:** Pending
5. **Classification / Product Code:** Unclassified / NPM
6. **Labeling, User Manual, Advertising Literature:** See Label and Package
7. **Intended Use:**

Intended for use in dental surgery.
The products may be used in surgical procedures such as:
* Augmentation or reconstructive treatment of alveolar ridge
* Filling of periodontal defects
* Filling of defects after root resection, apicocectomy, and cystectomy
* Filling of extraction sockets to enhance preservation of the alveolar ridge
* Elevation of maxillary sinus floor
* Filling of periodontal defects in conjunction with products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR)
* Filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration

8. **Substantial Equivalence**

-
-Predicate Device
SE Number: K033815
Product name: BIO-OSS®, BIO-OSS®) Blocks, BIO-OSS® Collagen
Company: Geistlich Pharma Ag.
The subject device and predicate devices are substantially equivalent. All have the same intended use…..

It is our intent that the marking of this device is considered confidential information and is to be treated as such by the FDA.

1415-1441 Gardena Ave,
Glendale California 91204 USA
e-Mail: pats0433@yahoo.com
Phone: 213-626-1544 FAX: 213-626-1548

We would appreciate your earliest attention to this 510K submission. If you have any question or comments, please feel free to contact me at any time.

Very truly yours,

/ Daniel Nam
Authorized Agent for
NIBEC Co., Ltd
and 510K Applicant.

PREMARKET NOTIFICATION

TRUTHFUL AND ACCURATE STATEMENT

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as President of NIBEC Co., Ltd. I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

(Signature)

Chong-Pyong.Chung/President

2011-10-02

(Date)

SCREENING CHECKLIST
FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS

510(k) Number: _____

The cover letter clearly identifies the type of 510(k) submission as (Check the appropriate box):

☐ Special 510(k) - Do Sections 1 and 2

☐ Abbreviated 510(k) - Do Sections 1, 3 and 4

☒ Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present or Adequate	Missing or Inadequate
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510)] Manual.	○	
Table of Contents.	○	
Truthful and Accurate Statement.	○	
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	○	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	○	
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510)] Manual.	○	
Statement of Indications for Use that is on a separate page in the premarket submission.	○	
Substantial Equivalence Comparison, including comparisons of the new device with the predicate in areas that are listed on page 3-4 of the Premarket Notification [510)] Manual.	○	
510(k) Summary or 510(k) Statement.	○	
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	○	
Identification of legally marketed predicate device. *	○	
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]	N/A	
Class III Certification and Summary. **	N/A	
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]	N/A	
510(k) Kit Certification ***	N/A	

* - May not be applicable for Special 510(k)s.

** - Required for Class III devices, only.

*** - See pages 3-12 and 3-13 in the Premarket Notification [510)] Manual and the Convenience Kits Interim Regulatory Guidance.

Section 2: Required Elements for a SPECIAL 510(k) submission:

	Present	Inadequate or Missing
Name and 510(k) number of the submitter's own, unmodified predicate device.		
A description of the modified device and a comparison to the sponsor's predicate device.		
A statement that the intended use(s) and indications of the modified device, as described in its labeling are the same as the intended uses and indications for the submitter's unmodified predicate device.		
Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device.		
A Design Control Activities Summary that includes the following elements (a-c):		
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.		
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.		
c. A Declaration of Conformity with design controls that includes the following statements:		
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.		
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.		

Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, SEE Required Elements for a Declaration of Conformity to a Recognized Standard, which is posted with the 510(k) boilers on the H drive.]		
For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has not been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device and any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

* - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:	0	
b) Sterilization and expiration dating information:	0	
i) sterilization process	0	
ii) validation method of sterilization process	0	
iii) SAL	N/A	
iv) packaging	N/A.	
v) specify pyrogen free	N/A	
vi) ETO residues	0	
vii) radiation dose	N/A	
viii) Traditional Method or Non-Traditional Method	Traditional	
c) Software Documentation:	N/A	

Items with checks in the “Present or Adequate” column do not require e additional information from the sponsor. Items with checks in the “Missing or Inadequate” column must be submitted before substantive review of the document.

Passed Screening _____Yes _____No
Reviewer:_____
Concurrence by Review Branch:_____

Date:_____

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the “A Suggested Approach to Resolving Least Burdensome Issues” document. It is available on our Center web page at:
http://www.fda.gov/cdrh/modact/leastburdensome.html

Indications for Use

510(k) Number (if known):

Device Name: OCS-B

Indications for Use:

OCS-B is intended for use in dental surgery.
The products may be used in surgical procedures such as:

* Augmentation or reconstructive treatment of alveolar ridge
* Filling of periodontal defects
* Filling of defects after root resection, apicocectomy, and cystectomy
* Filling of extraction sockets to enhance preservation of the alveolar ridge
* Elevation of maxillary sinus floor
* Filling of periodontal defects in conjunction with products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR)
* Filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Food and Drug Administration
Center for Devices and Radiological Health
9200 Corporate Blvd. (HFZ-401)
Rockville, Maryland 20850

RE: Attestation Statement to Safety and Effectiveness of OCS-B

Dear Sirs:

I certify that, in my capacity as President of NIBEC CO LTD. I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61

(Signature)

Chong-Pyong.Chung/ resident (Typed Name)

2011-05-02
(Date)

Form Approved: OMB No. 0910 0120; Exp rat on Date: 8/31/10

Department of Hea th and Human Serv ces
Food and Drug Adm n strat on

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☑ Trad t ona ☐ Spec a ☐ Abbrev ated

STANDARD TITLE [1]

EN ISO10993-10 (2002): Biological Evaluation of Medical Devices-Part 10: Tests for Irritation and Delayed-type Hypersensitivity

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3]	# 2-87	
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 tests? 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 and 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 for CDRH Guidance Documents can be found at www fda gov/cdrh/guidance html

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

EN ISO 1993-10 (2002): Biological Evaluation of Medical Devices-Part 10: Tests for Irritation and Delayed-type Hypersensitivity

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Test report	Biocompatibility Test Report	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

Test report No 2005-MBK-88

JUSTIFICATION

No Delayed-type hypersensitivity

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Test report	Biocompatibility Test Report	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

Test report No 2005-MBK-88

JUSTIFICATION

The requirement standard met

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

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

* For comp eteness st a sect ons of the standard and nd cate whether conformance s met. If a sect on s not app cab e (N/A) an exp anat on s needed under "just f cat on." Some standards nc ude opt ons, so s m ar to dev at ons, the opt on chosen needs to be descr bed and adequate y just f ed as appropr ate for the subject dev ce. Exp anat on of a dev at ons or descr pt on of opt ons se ected when fo ow ng a standard s requ red under "type of dev at on or opt on se ected," "descr pt on" and "just f ca- t on" on the report. More than one page may be necessary.

◆ Types of dev at ons can nc ude an exc us on of a sect on n the standard, a dev at on brought out by the FDA supp ementa nformat on sheet (SIS), a dev at on to adapt the standard to the dev ce, or any adaptat on of a sect on.

Paperwork Reduction Act Statement

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Rockville, MD 20850

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Form Approved: OMB No. 0910 0120; Exp rat on Date: 8/31/10

Department of Hea th and Human Serv ces
Food and Drug Adm n strat on

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☑ Trad t ona ☐ Spec a ☐ Abbrev ated

STANDARD TITLE [1]

EN ISO10993-5 (1999): Biological Evaluation of Medical Devices-Part 5: Tests for In Vitro cytotoxicity

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3]	# 2-64	
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 tests? 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 and 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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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Test report	Biocompatibility Test Report	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

Test report NO 2005-MBK-88

JUSTIFICATION

Slightly cytotoxicity and the requirement standard ISO 10993-5 met

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 comp eteness st a sect ons of the standard and nd cate whether conformance s met. If a sect on s not app cab e (N/A) an exp anat on s needed under "just f cat on." Some standards nc ude opt ons, so s m ar to dev at ons, the opt on chosen needs to be descr bed and adequate y just f ed as appropr ate for the subject dev ce. Exp anat on of a dev at ons or descr pt on of opt ons se ected when fo ow ng a standard s requ red under "type of dev at on or opt on se ected," "descr pt on" and "just f ca- t on" on the report. More than one page may be necessary.

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STANDARDS DATA REPORT FOR 510(k)s

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TYPE OF 510(K) SUBMISSION

☑ Trad t ona ☐ Spec a ☐ Abbrev ated

STANDARD TITLE [1]

ISO 10993-11:2006, Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3]	# 2-118	
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 tests? 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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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

ISO 10993-11:2006, Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Test report	Biocompatibility Test Report	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

Acute Systemic Toxicity Test

DESCRIPTION

Test report NO 2005-MBK-88

JUSTIFICATION

Met the requirement standard ISO 10993-11 met

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 comp eteness st a sect ons of the standard and nd cate whether conformance s met. If a sect on s not app cab e (N/A) an exp anat on s needed under "just f cat on." Some standards nc ude opt ons, so s m ar to dev at ons, the opt on chosen needs to be descr bed and adequate y just f ed as appropr ate for the subject dev ce. Exp anat on of a dev at ons or descr pt on of opt ons se ected when fo ow ng a standard s requ red under "type of dev at on or opt on se ected," "descr pt on" and "just f ca- t on" on the report. More than one page may be necessary.

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TYPE OF 510(K) SUBMISSION

☑ Trad t ona ☐ Spec a ☐ Abbrev ated

STANDARD TITLE [1]

ISO 10993-6:2007, Biological evaluation of medical devices -- Part 6: Tests for local effects after implantation

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3]	# 2-120	
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 tests? 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: _____

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

ISO 10993-6:2007, Biological evaluation of medical devices -- Part 6: Tests for local effects after implantation

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Test report	Biocompatibility Test Report	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

Implantation Test

DESCRIPTION

Test report NO SNUH-MCEC-050402301

JUSTIFICATION

Met the requirement standard ISO 10993-6

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 comp eteness st a sect ons of the standard and nd cate whether conformance s met. If a sect on s not app cab e (N/A) an exp anat on s needed under "just f cat on." Some standards nc ude opt ons, so s m ar to dev at ons, the opt on chosen needs to be descr bed and adequate y just f ed as appropr ate for the subject dev ce. Exp anat on of a dev at ons or descr pt on of opt ons se ected when fo ow ng a standard s requ red under "type of dev at on or opt on se ected," "descr pt on" and "just f ca- t on" on the report. More than one page may be necessary.

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11.1 PACKAING

11.1.1 Description of Packaging

(b)(4)

(b)(4)

Lot number, Expiry date, Manufacturer, Product code, Sterilization method, and Package inserts are supplied on the package.

The final package is carton box for shipment.

Damaged packaging may indicate the presence of unsafe products and should not be used until careful inspection. If inner package or outer package is damaged, the product should not be used and should be returned.
Once opened, the product should never be re-sterilized or re-used.

OCS-B products' packaging was qualified for shelf life and stability.

11.1.2 General packaging steps:

(b)(4)

11.1.3 Raw material of Packaging material

- Delivery: *On Cartons*

- Packaging materials:

  (1) Primary Package:

Content	Container	Component	Specification
OCS-B	Vial package	Glass Rubber	5ml Vial OP
OCS-B	Bowl type	Glass PS sheet	Octadon polystyrene
OCS-B	Syringe type	COC Rubber A push stick CAP	Topas - PP PP

(2) Secondary Package:

Content	Container	Component	Specification
OCS-B	Blister package	Blister Blister label	PET container Tyvek

(3) Tertiary Package:

Content	Container	Component	Specification
OCS-B	Paper Box	White card	Printed (green) card

(4) Final Package:

Content	Container	Component	Specification
OCS-B	Box	Corrugated cardboard	Export

11.2 LABELLING

11.2.1 Label Description

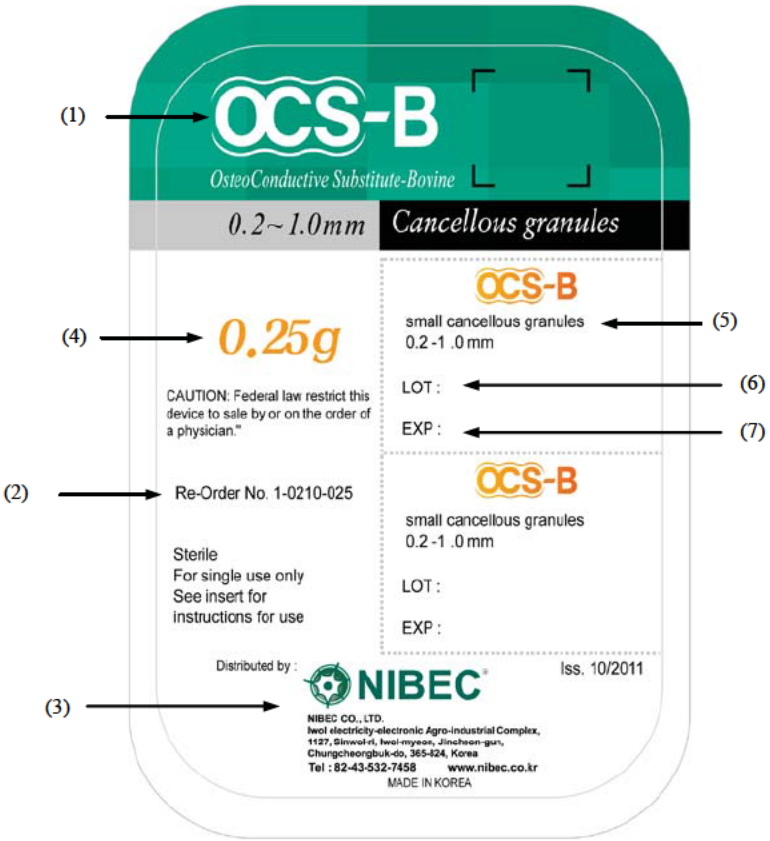
This section includes labelling information for ***OCS-B*** products manufactured by **NIBEC.**

The labelling system for CE marked ***OCS-B*** is composed of a sticker (or print) on the outer single pouch, stickers on carton box, package information insert, variable according to different applicators.
The symbols used in the indications conform to EN980:2008.

11.2.2 OCS-B of Labelling

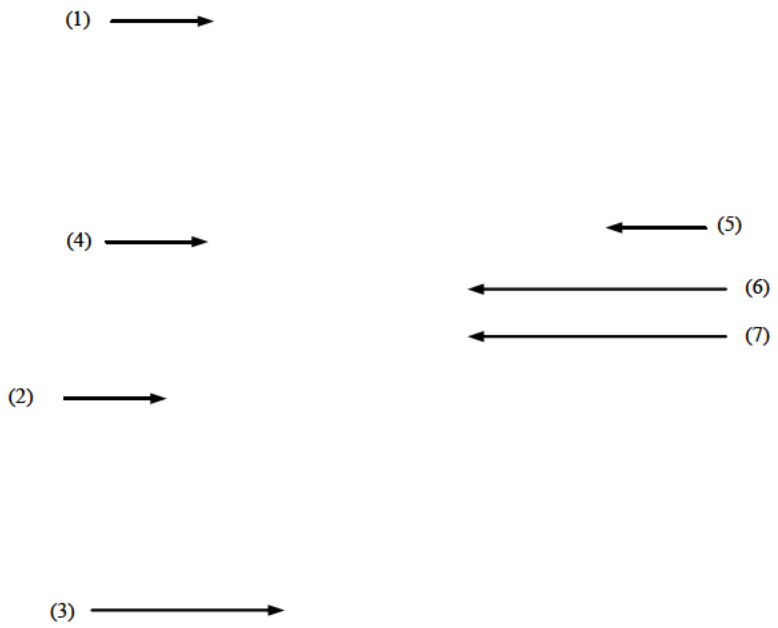
1) *Label description of laparoscopic applicators of OCS-B for sticker on Tyvek.*

- Vial Type



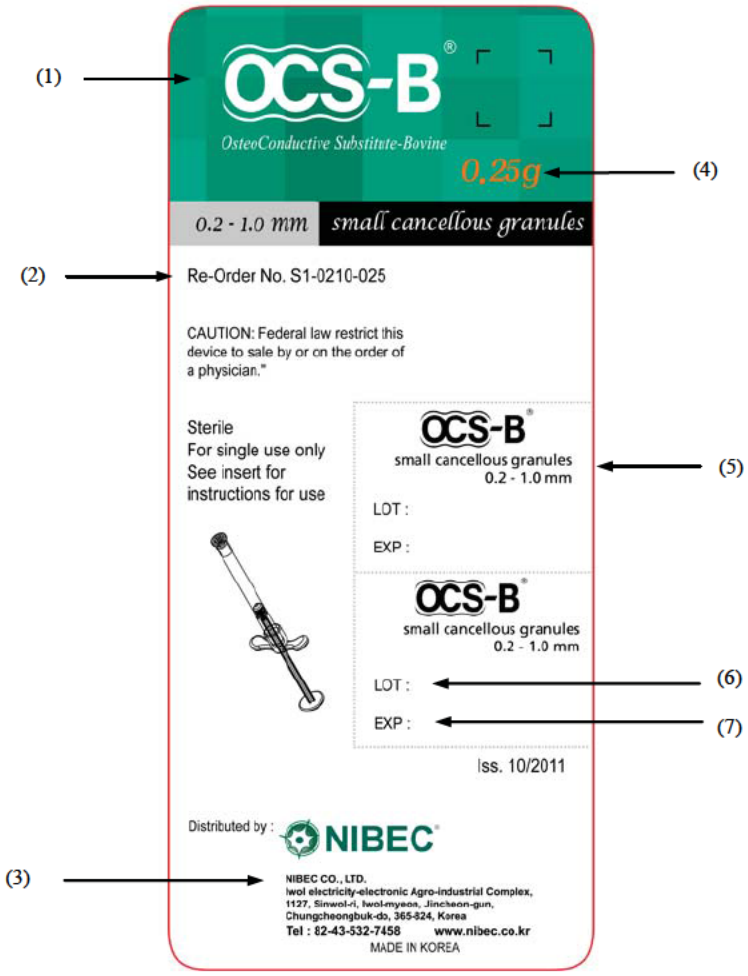
(1) Product name
(2) Catalogue number
(3) Distributor Identification
(4) Weight
(5) Particle size and type (cancellous bone and cortical bone)
(6) Lot number
(7) Expiry date

- **Bowl type**



(1) Product name
(2) Catalogue number
(3) Distributor Identification
(4) Weight
(5) Particle size and type (cancellous bone and cortical bone)
(6) Lot number
(7) Expiry date

- **Syringe type**



(1) Product name
(2) Catalogue number
(3) Distributor Identification
(4) Weight
(5) Particle size and type (cancellous bone and cortical bone)
(6) Lot number
(7) Expiry date

8.2.2h: *Label description of OCS-B for sticker (or print) on paper box*

- Vial Type

(1) Product name
(2) Catalogue number
(3) Manufacturer
(4) Caution Statement
(5) Distributor Identification
(6) Weight
(7) Particle size
(8) Type(cancellous bone and cortical bone)
(9) Lot number
(10) Expiry date

- **Bowl type**

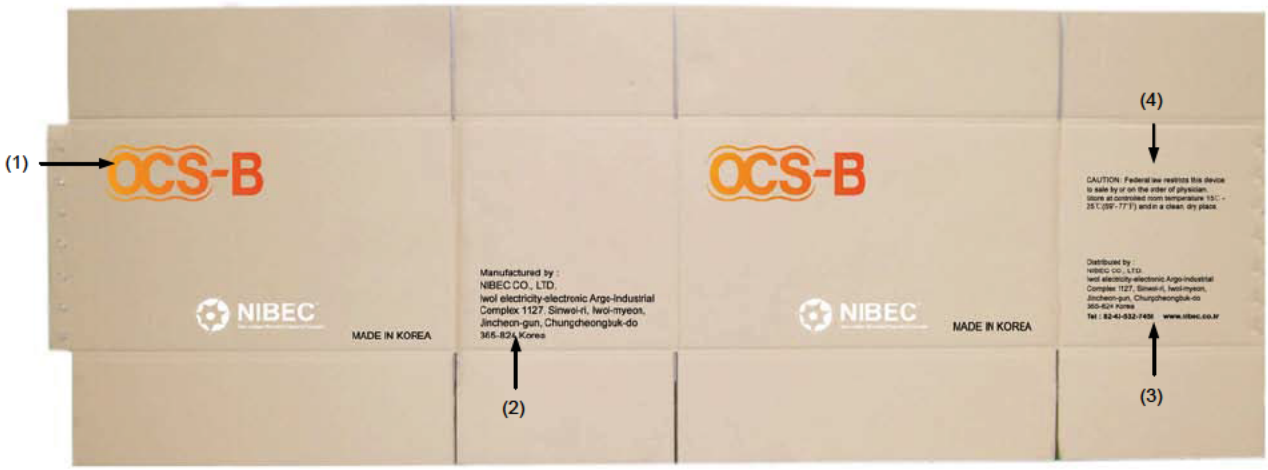
(1) Product name
(2) Catalogue number
(3) Manufacturer
(4) Caution Statement
(5) Distributor Identification
(6) Weight
(7) Particle size
(8) Type(cancellous bone and cortical bone)
(9) Lot number
(10) Expiry date

- Syringe type

(1) Product name
(2) Catalogue number
(3) Manufacturer
(4) Caution Statement
(5) Distributor Identification
(6) Weight
(7) Particle size
(8) Type(cancellous bone and cortical bone)
(9) Lot number
(10) Expiry date

8.2.2j: *Label description of standard kit for sticker on outer (larger) carton box (Front label)*

- Vial Type (= Bowl type, = Syringe type)



(1) Product name
(2) Manufacturer
(3) Distributor Identification
(4) Caution Statement

11.3 Instruction for Use

- After exposure of the bony defect with a full thickness mucoperiosteal flap, all granulation tissue must be carefully removed.
- Mix OCS-B® with autogenous bone, osseous coagulum, patient's blood or sterile normal saline. If large maxillofacial defects are present, OCS-B® should be mixed with autogenous bone in a ratio of approximately 1:1
- In order to assure the formation of new bone, OCS-B® should only be placed in direct contact with well vascularized bone. Cortical bone should be mechanically perforated, if necessary.
- Pack OCS-B® granules into the osseous defect using light to moderate pressure with a sterile instrument. Use of excessive force will result in crushing of particles and loss of trabecular architecture.
- Overfilling of the defects should be avoided.
- The mucoperiosteal flaps should be sutured to achieve primary closure without tension, if possible. Advancement of the flap or flap rotation may be applied in order to minimize the tension and achicve desired results. A surgical dressing, resorbable membrane or non-resorbable membrane may also be placed over the graft site as necessary.
- Sites grafted with OCS-B® should be allowed to heal approximately 6 months prior to implant placement

INDICATIONS FOR USE

510(K) Number:
Device Name: OCS-B® Natural Bone Mineral Matrix

INDICATIONS AND USAGE:
OCS-B® is recommended for:

- Augmentation or reconstructive treatment of the alveolar ridge.
- Filling of infrabony periodontal defects.
- Filling of defects after root resection, apicoectomy, and cystectomy.
- Filling of extraction sockets to enhance preservation of the alveolar ridge.
- Elevation of the maxillary sinus floor.
- Filling of periodontal defects in conjunction with products intend for Guided Tissue Regeneration(GTR) and Guided Bone Regeneration(GBR)
- Filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration(GBR).

Presciption Use ___ AND/OR Over-The-Counter Use
(Part 21 CER 801 Subpart D) (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Instruction for Use

-Main insert

Intended use of OCS-B

OCS-B® is recommended for:

- Augmentation or reconstructive treatment of the alveolar ridge.
- Filling of infrabony periodontal defects.
- Filling of defects after root resection, apicoectomy, and cystectomy.
- Filling of extraction sockets to enhance preservation of the alveolar ridge.
- Elevation of the maxillary sinus floor.
- Filling of periodontal defects in conjunction with products intend for Guided Tissue Regeneration(GTR) and Guided Bone Regeneration(GBR)
- Filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration(GBR).

Warning

1. After exposure of the bony defect with a full thickness mucoperiosteal flap, all granulation tissue must be carefully removed.
2. Mix OCS-B® with autogenous bone, osseous coagulum, patient's blood or sterile normal saline. If large maxillofacial defects are present, OCS-B® should be mixed with autogenous bone in a ratio of approximately 1:1
3. In order to assure the formation of new bone, OCS-B® should only be placed in direct contact with well vascularized bone. Cortical bone should be mechanically perforated, if necessary.
4. Pack OCS-B® granules into the osseous defect using light to moderate pressure with a sterile instrument. Use of excessive force will result in crushing of particles and loss of trabecular architecture.
5. Overfilling of the defects should be avoided.
6. The mucoperiosteal flaps should be sutured to achieve primary closure without tension, if possible. Advancement of the flap or flap rotation may be applied in order to minimize the tension and achicve desired results. A surgical dressing, resorbable membrane or non-resorbable membrane may also be placed over the graft site as necessary.
7. Sites grafted with OCS-B® should be allowed to heal approximately 6 months prior to implant placement

CAUTION: Federal law restrict this device to sale by or on the order of a physician.

NIBEC

NIBEC.CO.LTD. Iwol electricity-electronic Agro-industrial Complex, 1127, Sinwol-ri, Iwol-myeon, Jincheon-gun, Chungcheongbuk-do, 365-824, Korea
Tel : 82-43-532-7458, 82-80-765-1980 (Direct) Fax : 82-43-537-1714 www.nibec.co.kr

- **Vial Type**

OCS-B *Osteo Conductive Substitute-Bovine*

Component and characteristics

This bone graft material is natural hydroxyapatite derived from Korean bovine bone. OCS-B® is free of organic impurities including inflammatory protein, lipid and provides similar nanocrystal structure to human bone. OCS-B® facilitates osteoconduction due to its 3-dimensional porous structure and helps mineralization process. OCS-B® has wide application in bone regeneration in the defects associated with various dental disease, trauma and degeneration.

Uses

1) Properties

OCS-B® is natural bone mineral derived from bovine bone and is used as an adjuncitve therapy in recovering the bony detects.

2) Actions

It is used as an adjuncitve therapy in recovering the bony detects.

Instructions

1. After exposure of the bony detect with full-thickness mucoperiosoteal flap. all granulation tissue must be fully removed.
2. Mix OCS-B® with distilled water or sterile normal saline. OCS-B® should be mixed with autogenous bone in a ratio of 1:1 if large maxillofacial defects are present.

Use : mix the graft material with sterilized water or saline.the graft material is applide in defect area using the carrier (spatula)

3. OCS-B® should be placed into the bone cavity with sufficient contact with surrounding bone. The bone and soft tissue should be well vascularized.
4. Use of excessive force when placing OCS-B® into the bone cavity may result in crushing of particles. The contents of the bottle should be applied for single use only due to the infection after exposure of room air.
5. Overfilling of the defects should be avoided.
6. The flap should be sutured to achieve primary closure without any tension. Advanced flap or rotation flap may be applied to minimize the tension and achieve favorable results.
7. Sites grafted with OCS-B® should be allowed to heal approximately 6 months prior to implant placement.

* Mixing OCS-B® cancellous granules and OCS-B® cortical granules in a ratio of 1;1 in bone regeneration procedure may result in elevating the strength of new bone.

Contraindications

1) Contraindiction

should not be used in patients with:

1. Osteomyelitis at the surgical site or surrounding area
2. Metabolic diseases (diabetes, hyperparathyroidism, metablic disease of bone and connective tissue, osteomalacia)
3. Severe liver disease, severe renal dysfunction
4. Common user of steroid (High dose therapy with corticosteroids)
5. Vascular impairment at the implant site
6. Vascular disease

2) Precautions

1. Do not use the produce once the pack is opened. Do not re-sterilize.
2. Do not leave any granulation tissue or soft tissue in grafting area.
3. Do not use excessive force. It may result in crushing of particles.
4. Do not use after expiration date.

Adverse reactions

No adverse reactions have been reported.

How supplied

Cancellous granules	Weigt (g)	Size (mm)
1 -0210-025	0.25	0.2~1.0
1 -0210-050	0.5	
1 -0210-100	1.0	
1 -0210-200	2.0	
1 -1020-025	0.25	1.0~2.0
1 -1020-050	0.5	
1 -1020-100	1.0	
1 -1020-200	2.0	

Cortical granules	Weigt (g)	Size (mm)
2 -0210-025	0.25	0.2~1.0
2 -0210-050	0.5	
2 -0210-100	1.0	
2 -0210-200	2.0	
2 -1020-025	0.25	1.0~2.0
2 -1020-050	0.5	
2 -1020-100	1.0	
2 -1020-200	2.0	

Storage

The produce should be stored in a clean, dry place, at room temperature protective from direct sunlight. Keep the product in aseptic conditions until using the product.

= Do not reuse	= Lot number	= Manufacturer
= Use until year & month (Expiration date)	= Date of manufacture	= Authorized representative in the EC
= Catalogue number (Product code)	= Attention, see instruction for use	= Consult instructions for use
= Method of sterilization - Irradiation	= CE mark and identification number of Notified Body. Certified according with MDD (93/42/EEC)	

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Tel : 82-43-532-7458, 82-80-765-1980 (Direct) Fax : 82-43-537-1714 www.nibec.co.kr

- **Bowl type**

OCS-B® *Osteo Conductive Substitute-Bovine*

Component and characteristics

This bone graft material is natural hydroxyapatite derived from Korean bovine bone. OCS-B® is free of organic impurities including inflammatory protein, lipid and provides similar nanocrystal structure to human bone. OCS-B® facilitates osteoconduction due to its 3-dimensional porous structure and helps mineralization process. OCS-B® has wide application in bone regeneration in the defects associated with various dental disease, trauma and degeneration.

Uses

1) Properties

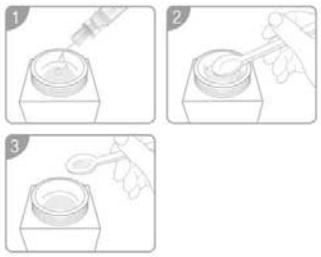
OCS-B® is natural bone mineral derived from bovine bone and is used as an adjuncitve therapy in recovering the bony detects.

2) Actions

It is used as an adjuncitve therapy in recovering the bony detects.

Instructions

1. After exposure of the bony detect with full-thickness mucoperiosoteal flap. all granulation tissue must be fully removed.
2. Mix OCS-B® with distilled water or sterile normal saline. OCS-B® should be mixed with autogenous bone in a ratio of 1:1 if large maxillofacial defects are present.



Use : mix the graft material with sterilized water or saline.the graft material is applide in defect area using the carrier (spatula)

3. OCS-B® should be placed into the bone cavity with sufficient contact with surrounding bone. The bone and soft tissue should be well vascularized.
4. Use of excessive force when placing OCS-B® into the bone cavity may result in crushing of particles. The contents of the bottle should be applied for single use only due to the infection after exposure of room air.
5. Overfilling of the defects should be avoided.
6. The flap should be sutured to achieve primary closure without any tension. Advanced flap or rotation flap may be applied to minimize the tension and achieve favorable results.
7. Sites grafted with OCS-B® should be allowed to heal approximately 6 months prior to implant placement.

* Mixing OCS-B® cancellous granules and OCS-B® cortical granules in a ratio of 1;1 in bone regeneration procedure may result in elevating the strength of new bone.

Contraindications

1) Contraindiction

should not be used in patients with:

1. Osteomyelitis at the surgical site or surrounding area
2. Metabolic diseases (diabetes, hyperparathyroidism, metablic disease of bone and connective tissue, osteomalacia)
3. Severe liver disease, severe renal dysfunction
4. Common user of steroid (High dose therapy with corticosteroids)
5. Vascular impairment at the implant site
6. Vascular disease

2) Precautions

1. Do not use the produce once the pack is opened. Do not re-sterilize.
2. Do not leave any granulation tissue or soft tissue in grafting area.
3. Do not use excessive force. It may result in crushing of particles.
4. Do not use after expiration date.

Adverse reactions

No adverse reactions have been reported.

How supplied

Cancellous granules	Weigt (g)	Size (mm)
S1-0210-025	0.25	0.2~1.0
S1-0210-050	0.5	
S1-0210-100	1.0	
S1-0210-200	2.0	
S1-1020-025	0.25	1.0~2.0
S1-1020-050	0.5	
S1-1020-100	1.0	
S1-1020-200	2.0	

Cortical granules	Weigt (g)	Size (mm)
S2-0210-025	0.25	0.2~1.0
S2-0210-050	0.5	
S2-0210-100	1.0	
S2-0210-200	2.0	
S2-1020-025	0.25	1.0~2.0
S2-1020-050	0.5	
S2-1020-100	1.0	
S2-1020-200	2.0	

Storage

The produce should be stored in a clean, dry place, at room temperature protective from direct sunlight. Keep the product in aseptic conditions until using the product.

② = Do not reuse
= Use until year & month (Expiration date)
REF = Catalogue number (Product code)
= Method of sterilization - Irradiation
LOT = Lot number
= Date of manufacture
= Attention, see instruction for use
CE 1935 = CE mark and identification number of Notified Body. Certified according with MDD (93/42/EEC)
= Manufacturer
EC REP = Authorized representative in the EC
= Consult instructions for use

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Tel : 82-43-532-7458, 82-80-765-1080 (Direct) Fax : 82-43-537-1714 www.nibec.co.kr

-syringe type

OCS-B Osteo Conductive Substitute-Bovine

Component and characteristics

This bone graft material is natural hydroxyapatite derived from Korean bovine bone. OCS-B® is free of organic impurities including inflammatory protein, lipid and provides similar nanocrystal structure to human bone. OCS-B® facilitates osteoconduction due to its 3-dimensional porous structure and helps mineralization process.OCS-B® has wide application in bone regeneration in the defects associated with various dental disease, trauma and degeneration.

Uses

1) Properties

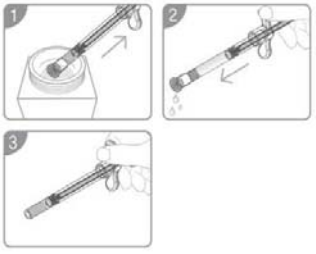
OCS-B® is natural bone mineral derived from bovine bone and is used as an adjuncitve therapy in recovering the bony detects.

2) Actions

It is used as an adjuncitve therapy in recovering the bony detects.

Instructions

1. After exposure of the bony detect with full-thickness mucoperiosteal flap. all granulation tissue must be fully removed.
2. Mix OCS-B® with distilled water or sterile normal saline. OCS-B® should be mixed with autogenous bone in a ratio of 1:1 if large maxillofacial defects are present.



Use : mix the graft material with sterilized water or saline.the graft material is applide in defect area using the carrier (spatula)

3. OCS-B® should be placed into the bone cavity with sufficient contact with surrounding bone. The bone and soft tissue should be well vascularized.
4. Use of excessive force when placing OCS-B® into the bone cavity may result in crushing of particles. The contents of the bottle should be applied for single use only due to the infection after exposure of room air.
5. Overfilling of the defects should be avoided.
6. The flap should be sutured to achieve primary closure without any tension. Advanced flap or rotation flap may be applied to minimize the tension and achieve favorable results.
7. Sites grafted with OCS-B® should be allowed to heal approximately 6 months prior to implant placement.

* Mixing OCS-B® cancellous granules and OCS-B® cortical granules in a ratio of 1;1 in bone regeneration procedure may result in elevating the strength of new bone.

Contraindications

1) Contraindiction

should not be used in patients with:

1. Osteomyelitis at the surgical site or surrounding area
2. Metabolic diseases (diabetes, hyperparathyroidism, metablic disease of bone and connective tissue, osteomalacia)
3. Severe liver disease, severe renal dysfunction
4. Common user of steroid (High dose therapy with corticosteroids)
5. Vascular impairment at the implant site
6. Vascular disease

2) Precautions

1. Do not use the produce once the pack is opened. Do not re-sterilize.
2. Do not leave any granulation tissue or soft tissue in grafting area.
3. Do not use excessive force. It may result in crushing of particles.
4. Do not use after expiration date.

Adverse reactions

No adverse reactions have been reported.

How supplied

Cancellous granules	Weigt (g)	Size (mm)
L1 -0210-010	0.1	0.2~1.0
L1 -0210-025	0.25	
L1 -0210-050	0.5	
L1 -1020-010	0.1	1.0~2.0
L1 -1020-025	0.25	
L1 -1020-050	0.5	

Cortical granules	Weigt (g)	Size (mm)
L2 -0210-010	0.1	0.2~1.0
L2 -0210-025	0.25	
L2 -0210-050	0.5	
L2 -1020-010	0.1	1.0~2.0
L2 -1020-025	0.25	
L2 -1020-050	0.5	

Storage

The produce should be stored in a clean, dry place, at room temperature protective from direct sunlight. Keep the product in aseptic conditions until using the product.

② = Do not reuse
= Use until year & month (Expiration date)
REF = Catalogue number (Product code)
STERILE R = Method of sterilization - Irradiation
LOT = Lot number
= Date of manufacture
= Attention, see instruction for use
CE 1023 = CE mark and identification number of Notified Body. Certified according with MDD(93/42/EEC)
= Manufacturer
EC REP = Authorized representative in the EC
= Consult instructions for use

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Tel : 82-43-532-7458, 82-80-765-1980 (Direct) Fax : 82-43-537-1714 www.nibec.co.kr

INDICATIONS FOR USE

510(K) Number: _____

Device Name: OCS-B®

INDICATIONS AND USAGE:

OCS-B® is recommended for:

- Augmentation or reconstructive treatment of the alveolar ridge.
- Filling of infrabony periodontal defects.
- Filling of defects after root resection, apicoectomy, and cystectomy.
- Filling of extraction sockets to enhance preservation of the alveolar ridge.
- Elevation of the maxillary sinus floor.
- Filling of periodontal defects in conjunction with products intend for Guided Tissue Regeneration(GTR) and Guided Bone Regeneration(GBR)
- Filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration(GBR).

Presciption Use _____ AND/OR Over-The-Counter Use _____

(Part 21 CER 801 Subpart D) (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

fjg

1.1 Product responsibility

1.1.1 Manufacturer

- Name: NIBEC Co., Ltd.
- Address: Iwol electricity-electronic Agro-industrial Complex, 1127, Sinwol-ri, Iwol-myeon, Jincheon-gun, Chungcheongbuk-do, Korea
- Tel: +82-43-532-7458
- Fax: +82-43-537-1714

1.1.2 EC Representative

- B & V Vouge
- Unit 28 Kingspark Business Centre, 152-178 Kingston Road, New Malden, Surrey, KT3 3ST U.K.

1.2 Product Overview

1.2.1 Product Name and model name

- Product Name: Bone Graft
- Model Name: OCS-B
- Annex 1 Code List

1.2.2 Description

This product is made from natural hydroxyapatite derived from bovine bone. The organic material is efficiently removed and does not show immune reaction. Also it uses bovine bone which has not shown and BSE(bovine spongiform encephalopathy) infection .
It can be applied to bony defect from various dental diseases, trauma and degeneration.

1.2.3 Intended Use

OCS-B Is intended for use in dental surgery.
The products may be used in surgical procedures such as:
* Augmentation or reconstructive treatment of alveolar ridge
* Filling of periodontal defects
* Filling of defects after root resection, apicocectomy and cystectomy
* Filling of extraction sockets to enhance preservation of the alveolar ridge
* Elevation of maxillary sinus floor
* Filling of periodontal defects in conjunction with products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR)
* Filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration

1.3 Product Classification

OCS-B is classified under Medical Device Directive (MDD, 93/42/EEC amended by 2007/47/EC) Annex IX as a **Class III device. Rule 17 under Anne IX** states:" All devices manufactured utilizing animal tissues or derivatives rendered non-viable are Class III except where such devices are intended to come into contact with intact skin only."

1.4 Harmonized Standards

EN ISO 14630:2009
Non-active surgical implants - General requirements (ISO 14630:2008)

EN ISO 10993-1:2009
Biological evaluation of medical devices - Part 1: Evaluation and testing (ISO 10993-1:2009)

EN ISO 22442-1:2007
Medical devices utilizing animal tissues and their derivatives - Part 1: Application of risk management (ISO 22442-1:2007)

EN ISO 22442-2:2007
Medical devices utilizing animal tissues and their derivatives - Part 2: Controls on sourcing, collection and handling (ISO 22442-2:2007)

EN ISO 22442-3:2007
Medical devices utilizing animal tissues and their derivatives - Part 3: Validation of the elimination and/or inactivation of viruses and transmissible spongiform encephalopathy(TSE) agents (ISO 22442-3:2007)

EN ISO 14971:2009
Medical devices - Application of risk management to medical devices (ISO 14971:2007)

EN 980:2008
Symbols for use in the labeling of medical devices

EN 1041:2008
Information supplied by the manufacturer with medical devices

EN ISO 14155-1:2009
Clinical investigation of medical devices for human subjects - Part 1: General requirements (ISO 14155-1:2003)

EN ISO 14155-2:2009
Clinical investigation of medical devices for human subjects - Part 2: Clinical investigation plans (ISO 14155-2:2003)

EN 556-1:2001
Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices

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

EN ISO 11737-2:2007
Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products

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9.1 Sterilizer information

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Address (b)(4)

Annex 9-1. Contract for sterilization

Annex 9-2-1. Sterilization Validation Report (b)(4)

Annex 9-2-1 Sterilization Repor (b)(4)

Annex 9-2-2. Sterilization Validation (b)(4)

Annex 9-2-2. Sterilization Validation Repor (b)(4)

Annex 9-2-3 Sterilization Report(Syringe)

Annex 9-3 Shelf-life Report

Annex 9-4 Sterilizer Certificate

Agreement for Contract sterilization

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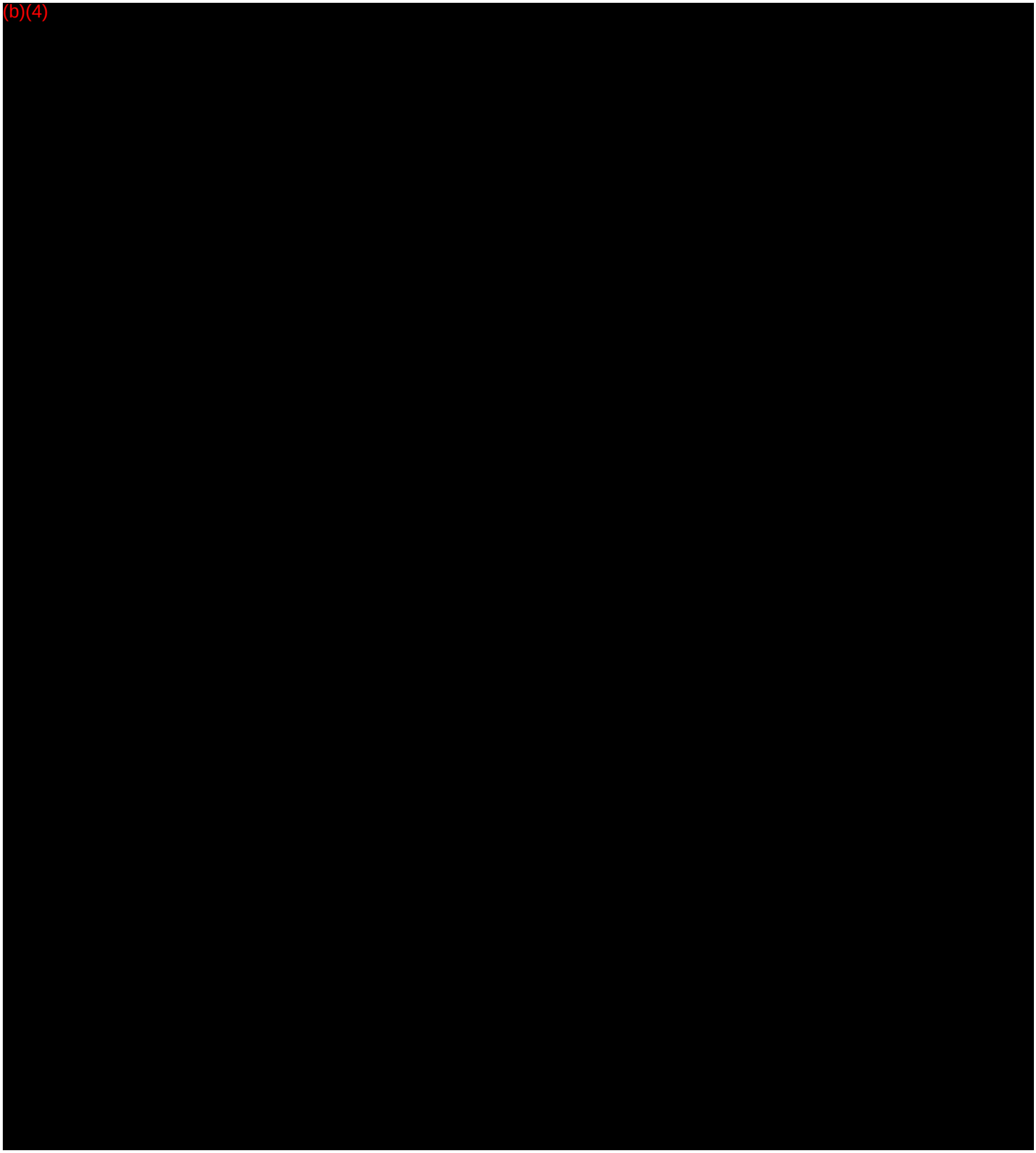

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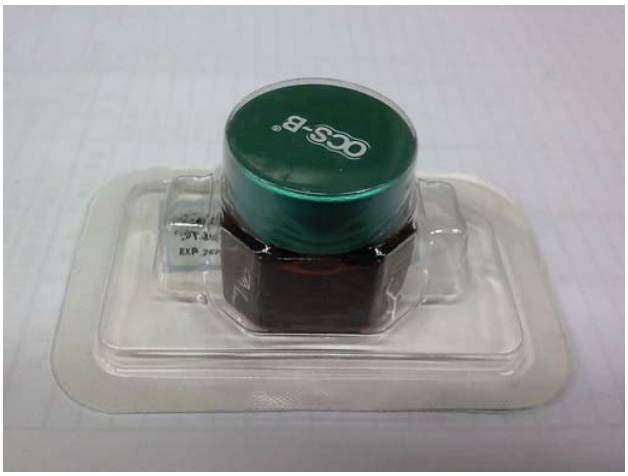

12 May 2010

NIBEC Co., Ltd.
중 앙 연 구 소

Address : #403 College of Dentistry, Seoul National University 28 Yongon-Dong, Chongno-Gu, Seoul, 110-749, Korea
Tel : 02-740-8757 Fax: 02-744-8732

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OB(accelerated stability) - Report - (b)(4)

16 August 2010

NIBEC Co., Ltd.
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Address : #403 College of Dentistry, Seoul National University 28 Yongon-Dong, Chongno-Gu, Seoul, 110-749, Korea
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OB(accelerated stability) - Report - (b)(4) [redacted]

12 May 2010

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510(k) Premarket Notification Database

Device Classification Name	bone grafting material, animal source
510(k) Number	K033815
Device Name	BIO-OSS, BIO-OSS BLOCKS AND BIO-OSS COLLAGEN
Applicant	GEISTLICH-PHARMA 1301 k street nw suite 600, east tower washington, DC 20005
Contact	peter s reichertz
Regulation Number	872.3930
Classification Product Code	NPM
Date Received	12/12/2003
Decision Date	01/15/2004
Decision	substantially equivalent (SE)
Classification Advisory Committee	Dental
Review Advisory Committee	Dental
Statement/Summary/Purged Status	Summary only
summary	summary
Type	Traditional
Reviewed by Third Party	No
Expedited Review	No

Database Updated 02/06/2009

[Code of Federal Regulations]
[Title 21, Volume 8]
[Revised as of April 1, 2008]
[CITE: 21CFR872.3930]

See Related Information

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H--MEDICAL DEVICES

PART 872 -- DENTAL DEVICES

Subpart D--Prosthetic Devices

Sec. 872.3930 Bone grafting material.

(a) *Identification* . Bone grafting material is a material such as hydroxyapatite, tricalcium phosphate, polylactic and polyglycolic acids, or collagen, that is intended to fill, augment, or reconstruct periodontal or bony defects of the oral and maxillofacial region.

(b) *Classification* . (1) Class II (special controls) for bone grafting materials that do not contain a drug that is a therapeutic biologic. The special control is FDA's "Class II Special Controls Guidance Document: Dental Bone Grafting Material Devices." (See 872.1(e) for the availability of this guidance document.)

(2) Class III (premarket approval) for bone grafting

materials that contain a drug that is a therapeutic biologic. Bone grafting materials that contain a drug that is a therapeutic biologic, such as biological response modifiers, require premarket approval.

(c) *Date premarket approval application (PMA) or notice of product development protocol (PDP) is required* . Devices described in paragraph (b)(2) of this section shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[70 FR 21949, Apr. 28, 2005]

Database Updated April 1, 2008

JAN 1 5 2004

K033815

510(k) Summary

BIO-OSS®

BIO-OSS® Blocks

BIO-OSS® Collagen

1. SPONSOR

Geistlich Pharma Ag
Bahnhofstrasse 40
CH-6110 Wolhusen
SWITZERLAND

Contact Person: Dr. Susana Wäsch, 011-41-41-49-25-630
Date Prepared: December 5, 2003

2. DEVICE NAME

Proprietary Name:	BIO-OSS®, BIO-OSS® Blocks, BIO-OSS® Collagen
Common/Usual Name:	Anorganic Bovine Bone Filling Material
Classification Name:	Bone Filling Material

3. PREDICATE DEVICES

BIO-OSS® (K871773, K952617, and K970321)
BIO-OSS® Blocks (K920508, K952618, and K970569)
BIO-OSS® Collagen (K974399)

4. INTENDED USE

BIO-OSS®, BIO-OSS Blocks and BIO-OSS® Collagen are recommended for:

- Filling of large oral and maxillofacial intra-osseous cavities

5. DEVICE DESCRIPTION

BIO-OSS®, BIO-OSS® Blocks, and BIO-OSS® Collagen are natural non-antigenic, porous bone mineral matrixes. They are produced by removal of all organic components from bovine bone. Due to its natural structure, BIO-OSS®, BIO-OSS® Blocks, and BIO-OSS® Collagen are physically and chemically comparable to the mineralized matrix of human bone. It is available as cortical granules and blocks.

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

BIO-OSS®, BIO-OSS® Blocks, and BIO-OSS® Collagen are substantially equivalent to Geistlich's existing products, BIO-OSS® Anorganic Bovine Bone (K871773, K952617, and K970321), BIO-OSS® Blocks (K920508, K952618, and K970569), and BIO-OSS®

Collagen (K974399). The only difference between the new products and the products previously cleared is that an alternative geographic source for the bovine bone is proposed to be added - Australia. The current source of bone is the United States. The European Union, in its Report on the Assessment of the Geographical BSE-risk of Australia, found Australia to have a level I Geographical BSE-risk ("GBR") - which means that it is highly unlikely that there is the presence of one or more cattle clinically or pre-clinically infected with the BSE agent in Australia. The United States has a level II GBR. It should be noted that Australia is not on the U.S. Department of Agriculture's list of countries affected with BSE. See 9 C.F.R. § 94.18. The company has performed a Risk Assessment per FDA Guidance to address traceability and pedigree of the herds. Therefore, using an alternative source of bovine bone will not negatively impact the products' safety or effectiveness.

With regard to the safety and effectiveness of the anorganic bovine bone used in BIO-OSS®, BIO-OSS® Blocks, and BIO-OSS® Collagen Geistlich incorporates by reference all of the information on the use of BIO-OSS®, BIO-OSS® Blocks, and BIO-OSS® Collagen in the above referenced 510(k) submissions.

BIO-OSS®, BIO-OSS® Blocks, and BIO-OSS® Collagen, as proposed to be sourced are substantially equivalent to the existing BIO-OSS®, BIO-OSS® Blocks, and BIO-OSS® Collagen products, in substance, function and intended use.

Based on the foregoing, Geistlich believes that the information and data herein submitted demonstrates not only that these versions of BIO-OSS®, BIO-OSS® Blocks, and BIO-OSS® Collagen are substantially equivalent to existing BIO-OSS®, BIO-OSS® Blocks, and BIO-OSS® Collagen products but also that these products have been shown to be safe and effective for the labeled indications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 5 2004

Geistlich-Pharma Ag
C/O Mr. Peter S. Reichertz
Sonnenschein Nath & Rosenthall LLP
1301 K Street NW
Suite 600, East Tower
Washington, D.C. 20005

Re: K033815
Trade/Device Name: BIO-OSS Granules, BIO-OSS Blocks and BIO-OSS Collagen
Regulation Number: None
Regulation Name: None
Regulatory Class: Unclassified
Product Code: NPM
Dated: December 8, 2003
Received: December 12, 2003

Dear Mr. Reichertz:

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.

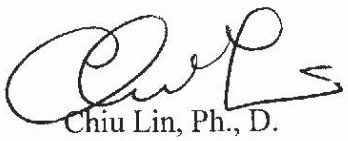
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4613. 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/dsma/dsmamain.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

K033815

Indications for Use

510(k) Number (if known): K033815

Device Name: BIO-OSS Granules, BIO-OSS Blocks and BIO-OSS Collagen

Indications for Use:

Augmentation or reconstructive treatment of alveolar ridge
Filling of periodontal defects
Filing of defects after root resection, apicoectomy, and cystectomy
Filing of extraction sockets to enhance preservation of the alveolar ridge
Elevation of maxillary sinus floor

Filling of periodontal defects in conjunction with products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR).

Filing of peri-implant defects in conjunction with products intended for Guided Bone Regeneration (GBR)

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

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

510(k) Number: K033815

25103138\V-1

Risk Management Plan

Product Name	bone graft material
Model Name	OCS-B

NIBEC Co., Ltd.

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Risk Management Report

Product Name	bone graft material
Model Name	(b)(4)

NIBEC Co., Ltd.

This document occur the effect from the date of approval.

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510(K) SUMMARY

[as required by 807.92(c)]

A.510k Number:

B. Applicant: Company name: PATS CORP
Address: 205 Broadway 718ste Los Angeles CA. USA

C. Proprietary and Established Names: **NIBEC CO LTD**
Address: Iwol electricity-electronic Agro-industrial Complex, 1127, Sinwol-ri, Iwol-myeon, Jincheon-gun, Chungcheongbuk-do, Korea

D. Regulatory Information

- Classification Name: Bone Filling Material
- Common / Usual Name: Anorganic Bovine Bone Filling Material
- Proprietary Name: OCS-B
- Classification / Product Code: Unclassified / NPM

E. Intended use

OCS-B is intended for use in dental surgery.
The products may be used in surgical procedures such as:
* Augmentation or reconstructive treatment of alveolar ridge
* Filling of periodontal defects
* Filling of defects after root resection, apicocectomy, and cystectomy
* Filling of extraction sockets to enhance preservation of the alveolar ridge
* Elevation of maxillary sinus floor
* Filling of periodontal defects in conjunction with products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR)
* Filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration
.

G. Substantial Equivalence Information

-Predicate Device
SE Number: K033815
Product name: BIO-OSS®, BIO-OSS®) Blocks, BIO-OSS® Collagen
Company: Geistlich Pharma Ag

The subject device and predicate devices are substantially equivalent. All have the same intended use…..

H. Performance Characteristics (If/when applicable)

1. See the Exhibits.

Test Results Report

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Final Report

Dental bone graft material (OCS-B) tests of moisture content

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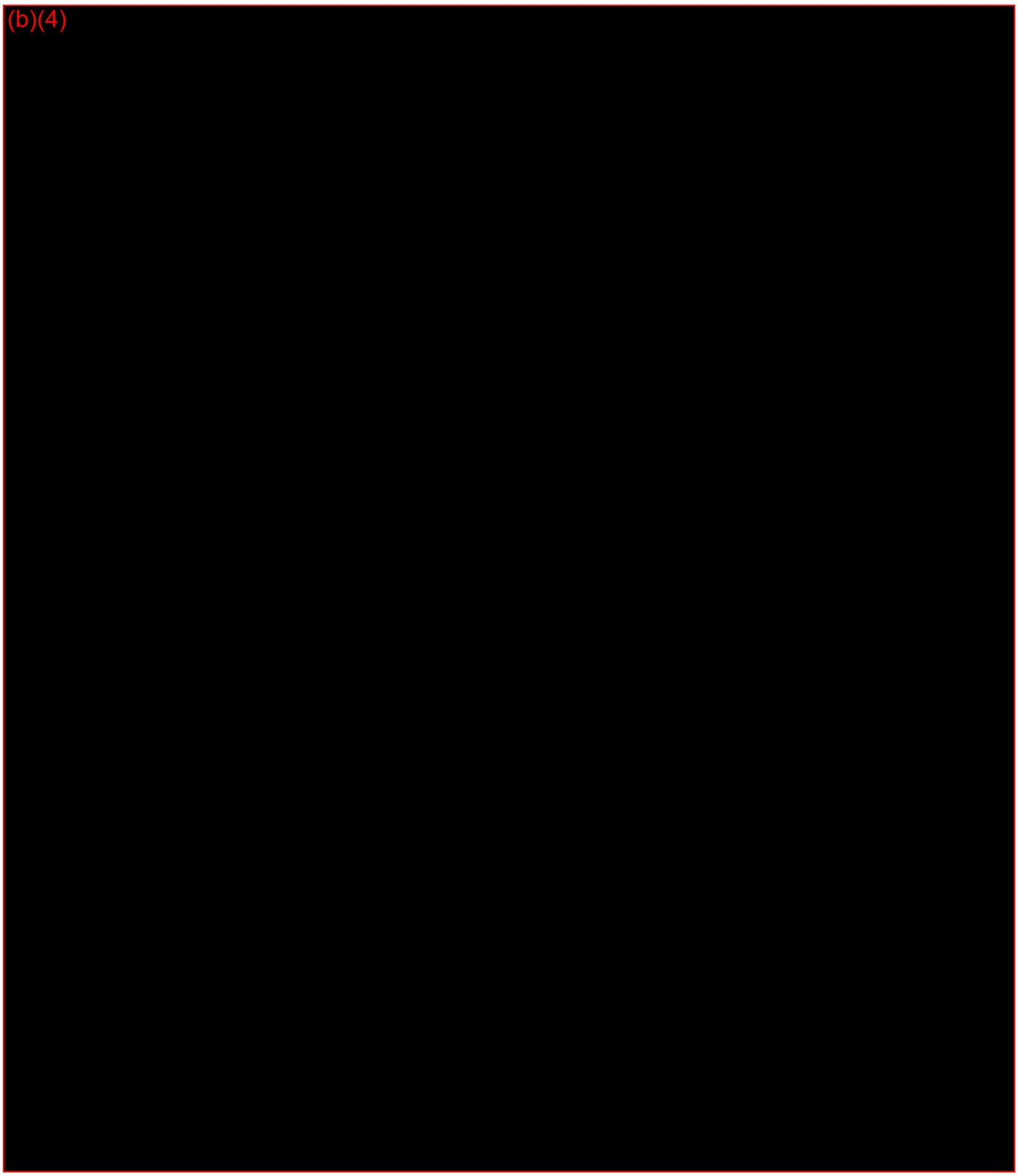
Study Report



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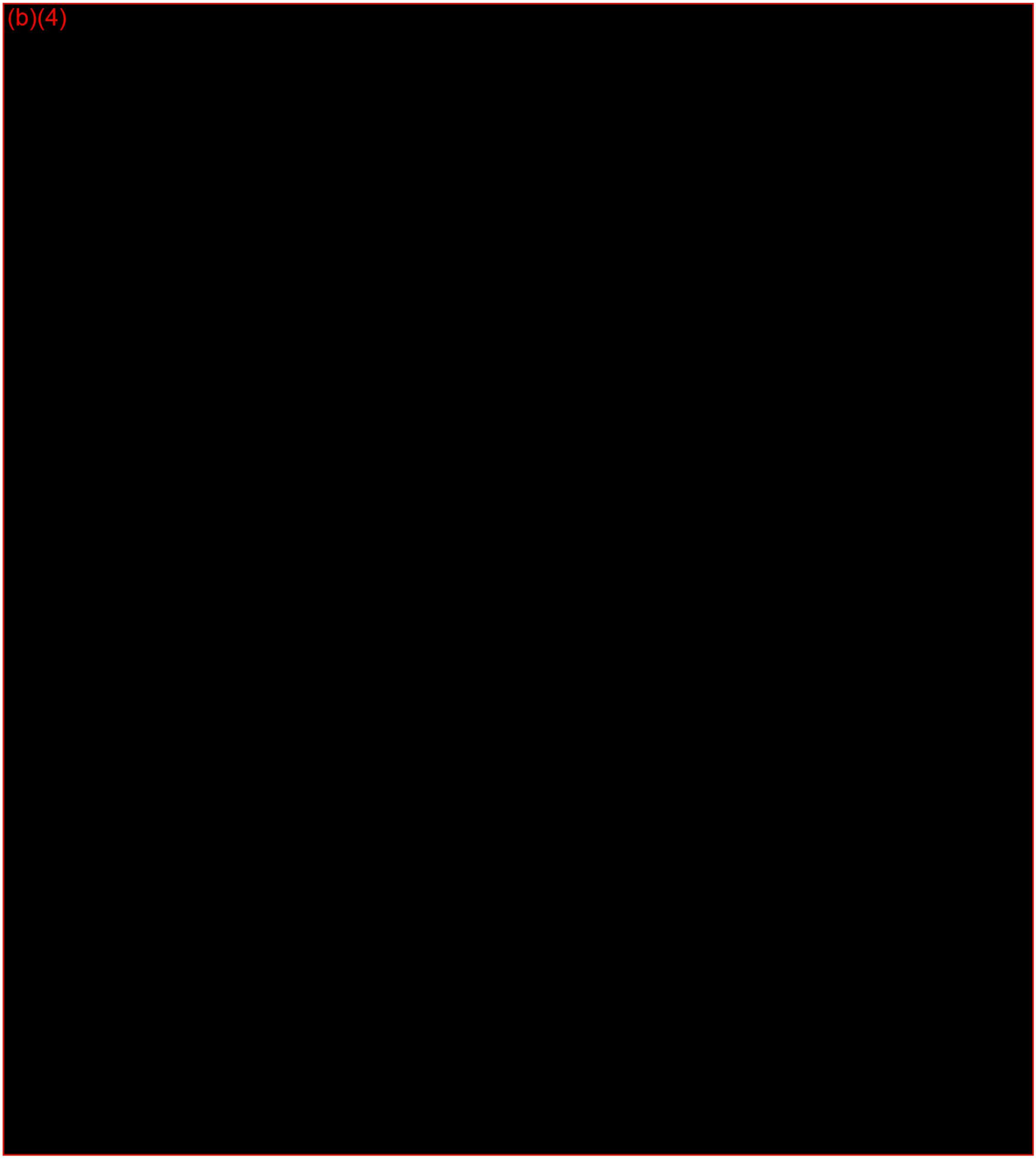
Study Report



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FINAL REPORT

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		작 성 일	

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Validation reports of the removal of protein that induce transmissible spongiform encephalopathy through de-fatting, deproteinization, and heat treatment process

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* * * COMMUNICATION RESULT REPORT (JAN. 17. 2013 9:53AM) * * *

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TRANSMITTED/STORED : JAN. 17. 2013 9:44AM FILE MODE OPTION	ADDRESS	RESULT	PAGE
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REASON FOR ERROR
E-1) HANG UP OR LINE FAIL
E-2) BUSY
E-3) NO ANSWER
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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

January 16, 2013

Nibec Company, Limited
C/O Mr. Daniel Nam
General Manager
Pats Corporation
4568 West 1st Street, Suite 104
LOS ANGELES CA 90004

Re: K113246
Trade/Device Name: OCS-B™
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: NPM
Dated: January 7, 2013
Received: January 14, 2013

Dear Mr. Nam:

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.

5

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Lauren Sikes

Subject: 510(k) Number K113246/S4

To: The Record

Please list CTS decision code SE

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☐ Hold (Additional Information or Telephone Hold).

☒ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

☐	NO	NSE for lack of predicate
☐	NI	NSE for new intended use
☐	NQ	NSE for new technology that raises new questions of safety and effectiveness
☐	NU	NSE for new intended use AND new technology raising new questions of safety and effectiveness
☐	NP	NSE for lack of performance data
☐	NS	NSE no response
☐	NL	NSE for lack of performance data AND no response
☐	NM	NSE pre-amendment device call for PMAs (515i)
☐	NC	NSE post-amendment device requires PMAs
☐	NH	NSE for new molecular entity requires PMA
☐	TR	NSE for transitional device

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):	YES	NO
Indications for Use Page *Attach IFU*	✓	
510(k) Summary /510(k) Statement *Attach Summary*	✓	
Truthful and Accurate Statement. *Must be present for a Final Decision*	✓	
Is the device Class III?		✓
If yes, does firm include Class III Summary? *Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)	✓	
Is this a combination product? (Please specify category N, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC		✓
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)		✓
Is this device intended for pediatric use only?		✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)	✓	
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?		✓
Is clinical data necessary to support the review of this 510(k)?	✓	
For United States-based clinical studies **only**: Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If study was		

conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)

Does this device include an Animal Tissue Source?

All Pediatric Patients age<=21

Neonate/Newborn (Birth to 28 days)

Infant (29 days -< 2 years old)

Child (2 years -< 12 years old)

Adolescent (12 years -< 18 years old)

Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)

Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)

Nanotechnology

Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html) *Contact OC.*

Regulation Number	**Class***	**Product Code**
872.3930	II	NPM

(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: Susan Runner (Branch Chief) DEB (Branch Code) 1/15/13 (Date)

Final Review: (Division Director) 1/16/13 (Date)

DEPARTMENT OF HEALTH AND HUMAN SERVICES MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Premarket Notification [510(k)] Review
Traditional

Substantially Equivalent

K113246/S004

Date: January 15, 2013

To: The Record Office: ODE

From: Lauren Giles, Biomedical Engineering Division: DAGRID

510(k) Holder: NIBEC Co., Ltd., of Chungcheongbuk-do, Korea

Device Name: *OCS-B* (K113246/S002)

Contact: Mr. Daniel Nam

Phone: 1-213-626-1544

Fax: 1-213-626-1548

Email: Pats0433@yahoo.com

I. Purpose and Submission Summary

NIBEC Co., Ltd., of Chungcheongbuk-do, Korea, has submitted a Premarket Notification (510(k)) to introduce into U.S. interstate commerce *OCS-B*, an organic bovine bone filling material. *OCS-B* is a prescription Class II medical device regulated under 21 CFR 872.3930 as a "Bone Grafting Material." The *OCS-B* is listed under product code NPM.

The submission for *OCS-B* consists of Form FDA 3674, Form FDA 3514, 510(k) Cover Letter, Truthful and Accurate Statement, Indication for Use, Safety and Effectiveness Statement, Screen Checklist, FDA Form 3674, Form 3654, Label and Package, User Manual, Product Description, Sterility Validation Report, Substantial Equivalence Report, Biocompatibility and Performance Test report, Risk Analysis Report, Clinical data, 510(k) Summary, Viral Inactivation report.

The primary mode of action for this device is grafting to dental defect to promote bone growth. The submission claims substantial equivalence to *BIO-OSS, BIO-OSS BLOCKS and BIO-OSS Collagen* (K033815).

The submission references the following standards in Form FDA 3514 but has provided Form FDA 3654 for all standards referenced.

Standard	Standard Title	Version
IEC 980	Graphical symbols for use in labeling of medical devices	2003
IEC 1041	Information supplied by the manufacturer with medical devices	1998
ISO 10993-1	Biological evaluation of medical devices – Part 1: Evaluation and Testing	2003
ISO 10993-5	Biological evaluation of medical devices – Part 5: Test for In Vitro Cytotoxicity	
ISO 10993-10	Biological evaluation of medical devices – Part 10: Test for irritation and delayed-type hypersensitivity	2002
ISO 10093-11	Biological evaluation of medical devices – Part 11: Test for system toxicity	2002
ISO 10093-6	Biological evaluation of medical devices – Part 6: Test for local effects after implantation	2007
ISO 14971	Medical Devices – Application of risk management to medical devices	2007

Reviewer's Notes:

- *In Form FDA 3514 the applicant lists the device classification as unknown; in addition on page 52 of the submission the applicant lists the device classification as Class III. However, under the NPM product code, the proposed device is consider Class II and contains special controls and FDA issued guidance document for "Dental Bone Grafting Material" and "Medical Devices Containing Materials Derived for Animal Sources."*
- *Form FDA 3654 has not provided for all the standards listed in Form FDA 3514. In addition, the submission references to several other standards on page 52 of the submission and in the sterilization and performance testing reports. Form FDA 3654 should be provided for all standard referenced or relied on in this submission.*

In S1, the applicant provided additional Form FDA 3654 for the standards referenced and relied upon.

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription)	X		
(Indicate if: OTC)			X
Truthful and Accuracy Statement	X		
Standards Form	X		

	YES	NO	N/A
Required Elements for 510(k) Summary (21 CFR 807.92)			
Clearly labeled "510(k) Summary"	X		

			YES	NO	N/A
	Submitter' s name, address, phone #, a contact person		X		
	Date the summary was prepared		X		
	The name of the device/trade name/common name/classification name		X		
	An identification of the legally marketed Predicate		X		
	Description of the subject device		X		
	Statement of intended use(identical to indications for use)		X		
	Technological	if same, a summary of comparison of technological characters	X		
		If different, a summary of how do they compare to the Predicate	X		
	Performance Data	Brief discussion of non-clinical data submitted, referenced, or relied on	X		
		Brief discussion of clinical data submitted, referenced, or relied on, including: ▪ Description upon whom the device was tested, ▪ Data obtained from the tests and especially: ▪ Adverse events and complications ▪ Other information for SE determination	X		
		Conclusion that data demonstrate SE	X		
Required Elements for <u>510(k) Statement</u> (21 CFR 807.93)					
	Signed verbatim statement				X

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?	X		
Does the device design use software?		X	
Is the device sterile?	X		
Is the device reusable (not reprocessed single use) and are "cleaning" instructions included for the end user?		X	

OCS-B, K113246, NIBEC Co., Ltd.

OCS-B is an anorganic xenogeneic bone grafting material. *OCS-B* is composed of bovine natural hydroxyapatite derived for Korean native cattle bone. OCS-B is provided in three types: a vial, bowl, or syringe. All three types are supplied as cancellous granules or cortical granules. The particle size of *OCS-B* ranges from (b)(4) The Ca/P ratio of *OCS-B* is (b)(4

The device description includes a step-by-step flow chart and narrative of the manufacturing process for *OCS-B*. (b)(4)

(b)(4)

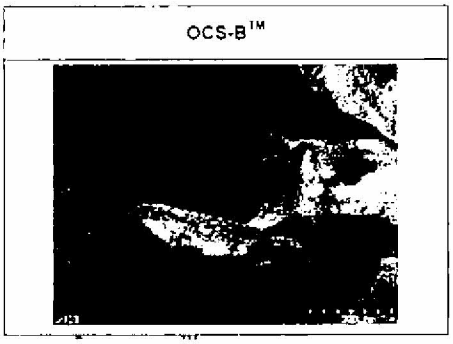
The risk analysis also provides addition details of *OCS-B*. (b)(4)

(b)(4)

Reviewer's Notes:

- *Korea is not listed on the FDA guidance document for "Medical Devices Containing Material Derived from Animal Source" as a country which BSE exist or presents a significant risk.*
- *The submission does not include any details on the chemical composition by weight or molar weight for the proposed device. In addition no details can be found on the raising, feeding, vaccination of the cattle.*
- *The submission does not specify the protein assay and what proteins are being tested.*

In S2, the applicant provided additional information to characterize the chemical and physical properties of OCS-B. OCS-B is an inorganic bone material primary composed of B-type hydroxyapatite. OCS-B is marketed as 0.2mm to 1.0mm and 1.0mm to 2.0mm granules in a variety of fill sizes. The degree of crystallization was tested by FT-IR and found to be below the commercial Low Crystalline Hydroxyapatite standard and primarily amorphous > 95%.



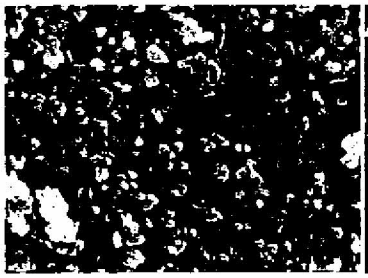


Figure 2
Low crystalline HAp(Aldrich)

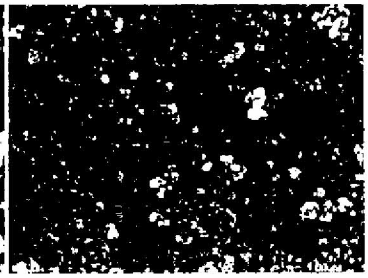


Figure 3
O CS-B™ (NIBEC Co., Ltd.)

12

An elemental analysis of the proposed device and predicate are provided below.

Test Item	OCS-B™ (lot# B101144)		Bio-Oss® (lot# 090245)	
	Unit	Result	Unit	Result
Pb	%	0	%	0
Cd	%	0	%	0
Ca	%	38.2000	%	38.1403
Mg	%	0.3666	%	0.3672
Na	%	0.3669	%	0.4391
Zn	%	0.0083	%	0.0075
P	%	17.6100	%	17.5260
Hg	%	0	%	0

Table 6 Specification for the Release of the Bulk Granules

Title	Method	Requirement
pH Test	pH measurement	pH of 7.0 ± 1.5
Protein assay (Deprotenization between thermal treatment Process)	Bradford assay	< 135 ppm

Table 7 Specification for the Release of the Final Product

Title	Method	Requirement
Appearance of product	Sealing condition, particle presence in the designated specification	White particulates in the sealed vial/bowl/syringe in the blisters
Appearance of granules	Particle size : ISO3310-1	> 90% of stated range (wt%)
	Weight variation : total weight of granules within be the container.	0.1g, 0.25g ± 20% 0.5g, 1g, 2g, 5g ± 10%
Water content	USP	< 5% (by wt%)
Label	Macrography (visual)	Check required label, and label condition
Protein assay	Bradford assay	< 135 ppm
Heavy Metals (as Pb)	USP	< 0.002%
Sterility	USP	Sterile
Bacterial Endotoxins(LAL)	USP	< 20.0 USP EU/vial

IV. Indications for Use

OCS-B® is recommended for:

- Augmentation or reconstructive treatment of the alveolar ridge.
- Filling of infrabony periodontal defects.
- Filling of defects after root resection, apicoectomy, and cystectomy.
- Filling of extraction sockets to enhance preservation of the alveolar ridge.
- Elevation of the maxillary sinus floor.
- Filling of periodontal defects in conjunction with products intend for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR).
- Filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration (GBR).

Reviewer's Notes:
The IFUS provided in the submission is not marked for prescription use. The IFUS is identical in wording and content to the declared predicate device.

V. Labeling

The submission includes draft labeling for the packaging and also contains draft Instructions for Use.

The *OCS-B* products contain several packaging labels including a Tyvek label, paper box, and outer carton box. The labeling include a product description (trade name, particle size, granule type, and weight), the manufacturer information, sterile, single use only, caution to read instructions, lot and expiration date, and the prescription statement as required by 21 CFR 801.109. The labeling contains no symbols and all text is written in the English language.

The submission also includes draft Instructions for Use. The main insert state that *OCS-B* should only be placed in well vascularized bone. *OCS-B* can be mixed with autogenous bone, osseous coagulum, patient's blood or sterile normal saline. For larger defects it should be mixed with autogenous bone in a 1:1 ratio. *OCS-B* should be placed with light/moderate pressure and the defects should not be overfilled. The instructions state the graft site should be allowed to heal for 6 months prior to implant placement.

In addition to the main insert, each type (vial, bowl, and syringe) of *OCS-B* contains directions. These direction include sections for Components and Characteristics, Uses, Instructions, Contraindications, Adverse Reactions, How Supplied, and Storage. The Instructions are similar to that in the main insert. The proposed device is contraindicated for use in people with metabolic diseases, liver disease, and vascular impairment among others. The "How Supplied" section details the all the variations of the granule, weight, and size of *OCS-B* provided for each type (vial, bowl, and syringe). *OCS-B* is to be stored at room temperature.

Reviewer's Notes:

- *The "Components and Characteristics" sections of the directions contain the following unsubstantiated claims:*
  - *"OCS-B is free of organic impurities including inflammatory proteins, lipid, and*

provides similar nanocrystal structure to human bone."
- *"OCS-B facilitates osteoconduction due to its 3-dimensional porous structure and helps mineralization process."*

- *The Uses section should be revised to state "Intended Use." The Intended Use should be identical to the Indications for Use Statement provided in the submission.*
- *The "Instructions" sections of the directions contain the following unsubstantiated claims:*
  - *"Mixing OCS-B cancellous granules and OCS-B cortical granules in a ratio of 1:1 in bone regeneration procedure may result in elevating the strength of new bone."*

In S2, the applicant provided revised labeling which removed the unsubstantiated claims. In addition, the Intended Use section was revised to Indications for Use and the wording is identical to the Indications for Use Statement provided in the submission. In S4, the applicant removed the word "natural" from the labeling. The labeling provided in S4 contains appropriate warning, precaution, and directions for use for the proposed device. No additional information is necessary for the determination of substantial equivalence.

VI. Sterilization/Shelf Life/Reuse

(b)(4)

[redacted]

18

VII. Biocompatibility

(b)(4)

(b)(4)

(b)(4)

(b)(4)

[redacted]

VIII. Software

OCS-B does not appear to contain any software as defined in the scope of FDA's "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". Therefore, software documentation and validation is not required for *OCS-B*.

IX. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

OCS-B does not appear to produce an EM field, utilize electricity, or produce a thermal effect. Therefore, EMC, electrical safety, and thermal safety are not applicable.

X. Performance Testing – Bench

(b)(4)

[redacted]

(b)(4)

(b)(4)

(b)(4)

22

(b)(4)

(b)(4)

XI. Performance Testing – Animal

(b)(4)

(b)(4)

(b)(4)

[redacted]

XII. Performance Testing – Clinical

(b)(4)

[redacted]

(b)(4)

(b)(4)

[redacted]

XIV. Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?	X		If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
3. Same Technological Characteristics?		X	If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?	X		If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?			If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?		X	If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?	X		If **NO** = Stop **NSE**
8. Performance Data Available?	X		If **NO** = Request Data
9. Data Demonstrate Equivalence?	X		Final Decision:

Note: See http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:

2. Explain why there is or is not a new effect or safety or effectiveness issue:
3. Describe the new technological characteristics:
4. Explain how new characteristics could or could not affect safety or effectiveness:
5. Explain how descriptive characteristics are not precise enough:
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
7. Explain why existing scientific methods can not be used:
8. Explain what performance data is needed:
9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

The submission seeks clearance for OCS-B, an anorganic, bovine derived bone grafting material. The submission claims substantial equivalence to BioOss (K033815). The IFUS of the proposed device is identical in wording and content to the declared predicate device[1]. However, OCS-B is derived from cattle raised in Korea and manufactured using a different process/facility than the declared predicate[3]. This raises concerns regarding viral inactivation, deproteinization/defatting of the material, biocompatibility of the device, and the ability of the proposed device to grow new bone in comparison to the predicate[6]. The applicant submitted numerous test report regarding the manufacturing process and biocompatibility of the proposed device. The applicant provided a detailed flow chart and narrative description of the manufacturing process. The manufacturing process and subsequent protein testing demonstrates removal of protein and fat from the mineral. Also submitted was viral inactivation testing. Viruses chosen were BVDV, IBR, PPV, and Reo-3. A consult from Dr. Peter Hudson concluded that the viral inactivation is significantly robust and assure adequate viral inactivation. The applicant also provided biocompatibility testing according to ISO 10993-1 for the device classification. The results of the biocompatibility testing demonstrated negative results in eliciting a immune response. The demonstrate equivalence performance in bone formation, the applicant submitted a comparison of the physical and chemical properties of the two devices as well as comparative canine animal testing. The results demonstrated a statistical difference in comparison to the negative control but equivalent bone formation to the predicate. The results of the extensive testing conducted by the company demonstrate that the proposed device is substantially equivalent to the declared predicate.

XV. Deficiencies

(b)(4)

[redacted]

(b)(4)

(b)(4)

31

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

Recommendation – Substantially Equivalent
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: Class II
Product Code: NPM

Digital Signature Concurrence Table	
Reviewer Sign-Off	Lauren M. Gilés 2013.01.15 15:31:59 -05'00'
Branch Chief Sign-Off	Susan Runner DDS, MA 2013.01.16 14:17:27 -05'00'
Division Sign-Off	Kwame O. Ulmer 2013.01.16 14:05:11 -05'00'

Sterile Devices in Premarket Notification [510(k)] Submissions

For:	Sterile, Single Use Devices (SUD)	Reusable Devices	Non-Sterile SUDs, to be sterilized once by a Health Care Facility	Reprocessed SUDs	Devices subject to Aseptic Processing and Filtration Methods
See the Guidance:	Updated 510(k) Sterility Review Guidance K90-1; August 30, 2002[1]	Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance, 1996.		MDUFMA, Validation Data in 510(k)s for Reprocessed SUDs[2]	See relevant guidance.

Sterilization Method	Additional Procedures for Non-traditional Sterilization Methods
Traditional	1. Refer to Infection Control Devices Branch (INCB) Chief for consideration. 2. INCB will advise ODE reviewing Division, and OC for appropriate action.
Non-traditional	Same as "1" and "2" above. In addition, INCB, the reviewing Division Director, ODE Deputy Director for Science and Regulatory Policy, and OC will determine the need for a Pre-Market Inspection
"Novel Non-traditional"	

For 510(k) devices proposed to be sterilized by Traditional and Non-traditional methods, FDA Reviewers should use the following review criteria to evaluate and document the sterilization information.

[1] *Updated 510(k) Sterility Review Guidance K90-1; Final Guidance for Industry and FDA Document Issued on: August 30, 2002*
[2] *Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single Use Devices*

1. Sterilant:	YES	NO
a. **Sterilization method** description (e.g., Steam, EtO, Radiation):	Gamma Radiation	
b. **Dose**, for radiation (e.g., 25 – 40 kGy):	25kGy	
c. **Sterilant residuals** remaining on the device: For EO, the maximum levels of residuals of EO and ethylene chlorhydrin that remain on the device (note: not to include ethylene glycol residual level because the recognized standard, "ANSI/AAMI/ISO 10993-7:1995 Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide sterilization residuals," does not include measurement of ethylene glycol residuals);	N/A	
2. A description of the Validation Method for the sterilization cycle (not data): (Citation of an FDA recognized standard is acceptable (e.g., ANSI/AAMI/ISO 11135))	ISO 11137-1,-2 VDMax	
3. Sterility assurance level (SAL): (e.g., 10^{-6} for all devices (except 10^{-3} for devices that contact intact skin))	10^{-6}	
4. Is it labeled "Pyrogen Free"?	Non-pyrogenic	
If so, a description of the method: (e.g., LAL (*Limulus* Amebocyte Lysate test))	LAL and rabbit testing	
5. A description of the packaging (not including package integrity test data):	See memo Sec. VI	

Giles, Lauren

From: PATSCORP [pats0433@yahoo.com]
Sent: Tuesday, January 15, 2013 4:58 AM
To: Giles, Lauren
Cc: dasue3635@naver.com; parkyj@snu.ac.kr
Subject: Re: OCS-B (K113246)_answer of additional information_3rd
Attachments: 510k Summary k113246.pdf; Indications for use k113246.pdf

Dear Lauren

Thank you for your prompt request.
Here I attached files you requested by email.
-Indication for use statement
-510k Summary.

Please check and let me know the next process.
I will expected to get final decision of this submission.
Thank you.

Best regards

Daniel Nam

Pan America Technical Service, Corp.
4568 West 1st Street, Suite 104
Los Angeles, CA 90004
Tel: 213-626-1544
Fax: 213-626-1548

From: "Giles, Lauren" <Lauren.Giles@fda.hhs.gov>
To: PATSCORP <pats0433@yahoo.com>
Sent: Tuesday, January 15, 2013 9:04 AM
Subject: RE: OCS-B (K113246)_answer of additional information_3rd

Mr. Nam,

Please also provide a revised 510(k) Summary containing a very brief, 1-2 sentence, description of the clinical case studies. Please provide this information in the "Brief Summary of Data Submitted" section. For example:

The submission includes a summary of seven individual case studies of *OCS-B*. The patients were treated for intra-bony periodontal defects. For each case study, the report includes baseline radiographs, radiographs at various time point, and core biopsy for histological evaluation. Histological and radiographic images demonstrate new bone growth.

Sincerely,
Lauren Giles
FDA/ODE/DAGRID/DEDB
phone: 301-796-9552

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From: Giles, Lauren
Sent: Monday, January 14, 2013 5:47 PM
To: 'PATSCORP'
Subject: RE: OCS-B (K113246)_answer of additional information_3rd

Mr. Nam,

Thank you for your thorough responses to the additional information request. I only have a few comments regarding the Indications for Use Statement and 510(k) Summary. Please make the following revisions to the 510 (k) Summary and Indications for Use Statement. Please send the revised Indications for Use Statement and 510 (k) Summary via email only by 9:00AM EST January, 15, 2013. Please provide the revised documents as soon as possible.

1. Please provide a revised Indications for Use Statement with the prescription use checked.
2. Please provide a revised 510(k) Summary which address the following:
   a. In the biocompatibility section of the Substantial Equivalence comparison, please remove the words safety and efficacy from the preclinical testing.
   b. The 510(k) Summary includes a section entitled "Brief Summary of Data Submitted in Support of Effectiveness and Safety." Please make the following changes:
      i. Please revise the title to state "Brief Summary of Data Submitted"
      ii. Please remove the sentence "Test results confirmed product safety" from the second paragraph of this section.
      iii. Please revised the sentence, In addition, the TSE inactivation validation as well as virus inactivation study result confirmed product safety" to remove the phrase "confirmed product safety". Please replace this phrase with "was conducted".
      iv. Please remove from the last paragraph of this section the phrase"..... and safe and effective for the proposed indications for use."
   c. Please remove the following sentence from the Conclusion: "Accordingly, OCS-B is expected to be safe and effective for its intended uses."

Sincerely,
Lauren Giles
FDA/ODE/DAGRID/DEDB
phone: 301-796-9552

From: PATSCORP [mailto:pats0433@yahoo.com]
Sent: Thursday, January 10, 2013 12:21 AM
To: Giles, Lauren
Cc: parkyj@snu.ac.kr; dasue3635@nibec.co.kr
Subject: RE: OCS-B (K113246)_answer of additional information_3rd

Dear Ms. Lauren Giles,

We've completed the response as well as its attachment documents to your request for further information of K113246.
We've sent the hard copy of the documents including the response as well as its attachments through air flight yesterday to the Document Mail Center.
Here I'm sending you the identical files to you for your review.

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Please check the file and let us know if you have any request and step to process.
Thank you.

Best regards

Daniel Nam

Pan America Technical Service, Corp.
4568 West 1st Street, Suite 104
Los Angeles, CA 90004
Tel: 213-626-1544
Fax: 213-626-1548

510(k) Summary

[as required by 807.92(c)]

Sponsor/Applicant

NIBEC Co., Ltd.

Iwol electricity-electronic Agro-industrial Complex, 1127, Sinwol-ri,

Iwol-myeon, Jincheon-gun, Chungcheongbuk-do, Korea

Phone : 82-10-2889-8590

Fax : 82-2-744-8732

Contact : Dr. Park, Yoon-Jeong

Date Prepared : JANUARY 07, 2013

Device Name and Identification

Proprietary Name : OCS-B™

Common / Usual Name : Bone Mineral Matrix

Anorganic Bovine Bone Grafting Material

Classification Name : Bone Grafting Material

Animal Source Dental Bone Grafting Material

Predicate Device

Bio-Oss® bone grafting material (K871773, K952617, K970321, K033815)

Manufactured by :

Geistlich Pharma AG

Bahnhofstrasse 40

CH-6110 Wolhusen

Switzerland

Device Category/Class

Device Class : Class II

Regulation Number : 21 C.F.R. 872.3930

Product Code : NPM

Indication for use

OCS-B™ cancellous and cortical granules are recommended for:

- Augmentation or reconstructive treatment of the alveolar ridge.
- Filling of infrabony periodontal defects.
- Filling of defects after root resection, apicoectomy, and cystectomy
- Filling of extraction sockets to enhance preservation of the alveolar ridge
- Elevation of maxillary sinus floor
- Filling of periodontal defects in conjunction with products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR)
- Filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration (GBR)

Device Description

OCS-B™ is a sterile, porous bone mineral matrix produced by the removal of organic compounds from bovine bone. It is supplied as cancellous (spongiosa) or cortical granules in a single use container, packaged in a secondary thermoform blister, and sterilized by γ-irradiation.

Basis for Substantial Equivalence

OCS-B™ and Bio-Oss® have a similar physical and chemical structure. Both are porous, biocompatible bone grafts that facilitate the formation and mineralization of new bone by the

osteoblast. As both products have same source of bone (bovine source) and similar process for removal of organic compounds, the product is substantially equivalent to Bio-Oss®.

The following table summarizes the basis for the Sponsor's substantial equivalence determination :

Table 1 Substantial Equivalence Comparison

ITEM	OCS-B™	Bio-Oss®
Intended Use	Used as an adjective therapy in restoring bony defects	Used as an adjective therapy in restoring bony defects
Target population	Human Oral, Periodontal	Human Oral, Periodontal
Dosage form	Granules contained in single use container	Granules contained in single use container
Granule sizes	0.2mm to 1.0mm or 1.0mm to 2.0 mm granules	0.25mm to 1.0mm or 1.0mm to 2.0 mm granules
Material	Anorganic derived osteoconductive hydroxyapatite bone mineral	Anorganic derived osteoconductive hydroxyapatite bone mineral
Source bone	Bovine bone	Bovine bone
Physical Morphology	Trabecular, interconnecting macro and micro pores	Trabecular, interconnecting macro and micro pores
Biocompatibility	Biocompatible, as demonstrated by : - Genotoxicity testing *(In vitro, In vivo)* - Intracutaneous reactivity testing - Maximization and sensitization testing - Pyrogen testing - Acute systemic toxicity testing - Cytotoxicity testing - Implantation testing - Preclinical safety and efficacy testing - Clinical case studies	Biocompatible (as demonstrated in published literature)

Performance	Bone formation	Bone formation
Compatibility w/other devices	Can be used with GTR membrane	Can be used with GTR membrane
Sterilization Process	Sterile by Gamma irradiation	Sterile by Gamma irradiation
Chemical Composition	Similar to Bio-Oss® based on chemical analysis, XRD, FT-IR and ICP analysis	Similar to OCS-B™ based on chemical analysis, XRD, FT-IR and ICP analysis
Anatomical sites	Oral, Periodontal	Oral, Periodontal
Non-pyrogenic	Yes	Yes
Shelf life	3 years	Determined by Manufacturer
Risk	Non-risk, as demonstrated by : - TSE inactivation Process Validation - Virus Clearance study - Analysis of residual solvent - Risk analysis - Cleaning Validation	-

Brief Summary of Data Submitted

The Sponsor evaluated the performance characteristics of OCS-B™ and Bio-Oss® with a thorough chemical and physical characterization. The physical and chemical characteristics of the products were found to be comparable. Further, in several animal studies, both products were found to grow new bone and be subsequently resorbed at similar rates. Finally, in a clinical case series, use of OCS-B™ resulted in defect healing and formation of new bone of sufficient quality to obtain dental implant placement. The submission includes a summary of seven individual case studies of OCS-B™. The patients were treated for intra-bony periodontal defects. For each case study, the report includes baseline radiographs, radiographs at various time point, and core biopsy for histological evaluation. Histological and radiographic images demonstrate new bone growth.

OCS-B™ was the subject of the full range of biocompatibility tests recommended in the FDA's "Class II. Special Controls Guidance Document : Dental Bone Grafting Devices" and in accordance with ISO 10993. Organic material has been removed from the product, and product specifications have been established to limit protein content. Throughout the risk analysis for each production step, for example, cleaning validation, the removal of organic solvent, the risk control was conducted during the manufacturing process. In addition, the

TSE inactivation validation as well as virus inactivation study result was conducted. Further, the product is sterilized to achieve a sterility assurance level SAL 1 x 10^{-6}.

Based on the information presented herein, it has been demonstrated that OCS-B™ is substantially equivalent to Bio-Oss®.

Conclusion

The OCS-B™ presents the same types of potential risks to consumers as the predicate device Bio-Oss®, and has controlled these risks in a similar manner. And biocompatibility tests and compatibility test show that the device meets the requirements of those standards. Literatures and post market experience show that the device is substantially equivalent. Comparison with the predicate device shows that the device has similar specification and performance.

Therefore, it is concluded that OCS-B™ are substantially equivalent to the predicate device.

Indications for Use

510(k) Number (if known):

Device Name: OCS-B™

Indications for Use:

OCS-B™ cancellous and cortical granules are recommended for:

- Augmentation or reconstructive treatment of the alveolar ridge.
- Filling of infrabony periodontal defects.
- Filling of defects after root resection, apicoectomy, and cystectomy
- Filling of extraction sockets to enhance preservation of the alveolar ridge
- Elevation of maxillary sinus floor
- Filling of periodontal defects in conjunction with products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR)
- Filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration (GBR)

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

MEMO TO THE RECORD
K113246/S3 Consult

DATE: 1/10/13
OFFICE: HFZ-410
DIVISION: DSORD/PRSB
FROM: Biologist
RE: Responses to deficiencies
CONSULT TO: Ms. Lauren Giles

Recommendation: The sponsor has provided adequate information to address the 6 deficiencies I previously recommended be sent to them. The information regarding the animal husbandry issues, the potential reagent toxicities, and the additional genotoxicity assessments adequately demonstrates the product – with respect to these specific issues – is safe, and is substantially equivalent in terms of safety to other class II bone void filler materials. I have no additional questions.

Review:
Previously, Ms. Giles requested consultation of the animal husbandry and reagent toxicity information pertaining to K113246. I identified 6 deficiencies – those questions, and the reviewed responses from the manufacturer follow (review comments in italicized font):

Deficiencies

(b)(4)

[redacted]

50

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

Peter L. Hudson
2013.01.10 18:50:23 -05'00'

Peter L. Hudson, Ph.D./Reviewer (Date)
Division of General and Restorative Devices
Plastic and Reconstructive Surgery Branch

MEMO TO THE RECORD

K113246/S1 Consult

DATE: 5/21/12
OFFICE: HFZ-410
DIVISION: DSORD/PRSB
FROM: Biologist
RE: Animal husbandry and viral inactivation review – responses to deficiencies
CONSULT TO: Ms. Lauren Giles

Recommendation: The sponsor provided additional information to address the deficiencies previously identified in my consult review – (b)(4)

(b)(4)

58

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

Peter L. Hudson, Ph.D. 7/25/12

Peter L. Hudson, Ph.D./Reviewer (Date)
Division of General and Restorative Devices
Plastic and Reconstructive Surgery Branch

(b)(4)

(b)(4)

(b)(4)

(b)(4)

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(b)(4)

(b)(4)

(b)(4)

MEMO TO THE RECORD
K113246 Consult

DATE: 3/23/12
OFFICE: HFZ-410
DIVISION: DSORD/PRSB
FROM: Biologist
RE: Animal husbandry and viral inactivation review
CONSULT TO: Ms. Lauren Giles

Recommendation: The information provided regarding the animal husbandry, manufacturing and viral inactivation validation lacks some detail. (b)(4) (b)(4) – additional information is recommended. The viral inactivation validation is significantly robust.

Review:
Ms. Giles has requested a consult review regarding the animal husbandry and viral inactivation information of premarket notification K113246:

Hi Peter,

Thanks you for stopping by earlier today to discuss this submission. I would like you get your opinion on the validity of the animal inspection certificate, viral inactivation report, and TSE report. The file, K113246, has been uploaded on image. The report can be found on the following pages.

---Animal Inspection Certificate: 66 and 68 (Section 5.3 of the risk analysis contains addition info starting on pg. 619)
---Manufacturing Process: pg. 106-111
---Viral Inactivation Report: pg. 987-1011
---TSE report: The TSE Inactivation Report begins on page 1026; however, the English protocol report begins is on page 1059-1097 and the English final report begins on page 1111.

Please let me know if you need any additional information.

Thanks again

Lauren Giles
FDA/ODE/DAGID/DEDB
phone: 301-796-9552

NIBEC Co., Ltd. has submitted a premarket notification regarding their bone grafting device, OCS-B. NIBEC is in South Korea. The product is identified as bone filling material.

Indications for Use

Indications for Use:

OCS-B is intended for use in dental surgery.
The products may be used in surgical procedures such as:

- **Augmentation or reconstructive treatment of alveolar ridge**
- **Filling of periodontal defects**
- **Filling of defects after root resection, apicocectomy, and cystectomy**
- **Filling of extraction sockets to enhance preservation of the alveolar ridge**
- **Elevation of maxillary sinus floor**
- **Filling of periodontal defects in conjunction with products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR)**
- **Filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration**

Device description

The product is described as consisting of "natural hydroxyapatite" derived from bovine bone. The sponsor asserts that "organic material is efficiently removed and does not show immune reaction". The sponsor also asserts that the bone is not contaminated with BSE.

Animal husbandry

Within the sponsor's risk analysis, section 5.3, Identification of characteristics related with the safety of medical device, the sponsor provided the following information:

- The bone graft material is made from bovine bone (*Bos Taurus coreana*, castrated animals) – specifically the thigh or femur bone
- The bone is obtained from cattle that are 3-7 years of age; the animals have been bred on Jelu island
- The animals are inspected by veterinarians

The sponsor provides an inspector/seal indication for their veterinary surgeon, Dr. Sung Hun Kim, Gangwon-do South Branch Veterinary Laboratory of Stock Epidemics Prevention and Sanitary. The sponsor may have the required animal husbandry information but they've either not provided it completely or it is within a section of the 510(k) I have not reviewed. I did go through their entire Risk Analysis.

Deficiency

(b)(4)

[redacted]

(b)(4)

(b)(4)

(b)(4)

(b)(4)

- (b)(4)
- [redacted]

You have provided extensive information regarding your manufacturing process, however, the actual concentrations of the various reagents used, i.e., methanols, chloroform, sodium hypochlorite, were not identified. Please provide this information.

Peter L. Hudson, Ph.D./Reviewer (Date)
Division of General and Restorative Devices
Plastic and Reconstructive Surgery Branch

(b)(4)

(b)(4)

(b)(4)

(b)(4)

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(b)(4)

(b)(4)

(b)(4)

[redacted]

Rakhi Dalal, Ph.D., Toxicologist, GHDB, DAGID
Consult Reviewer

April 24, 2012
Date

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Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Lauren Giles

Subject: 510(k) Number K113246

To: The Record

Please list CTS decision code TH

x Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

x Hold (Additional Information or Telephone Hold).

x Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

x	NO	NSE for lack of predicate
x	NI	NSE for new intended use
x	NQ	NSE for new technology that raises new questions of safety and effectiveness
x	NP	NSE for lack of performance data
x	NM	NSE requires PMA
x	NS	NSE no response
x	NH	NSE for another reason

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*		
510(k) Summary /510(k) Statement	*Attach Summary*		
Truthful and Accurate Statement.	*Must be present for a Final Decision*		
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			
Is clinical data necessary to support the review of this 510(k)? For United States-based clinical studies **only**: Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If study was conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			
All Pediatric Patients age<=21			

Neonate/Newborn (Birth to 28 days)			
Infant (29 days -< 2 years old)			
Child (2 years -< 12 years old)			
Adolescent (12 years -< 18 years old)			
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			
Nanotechnology			
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		

Regulation Number **Class*** **Product Code**

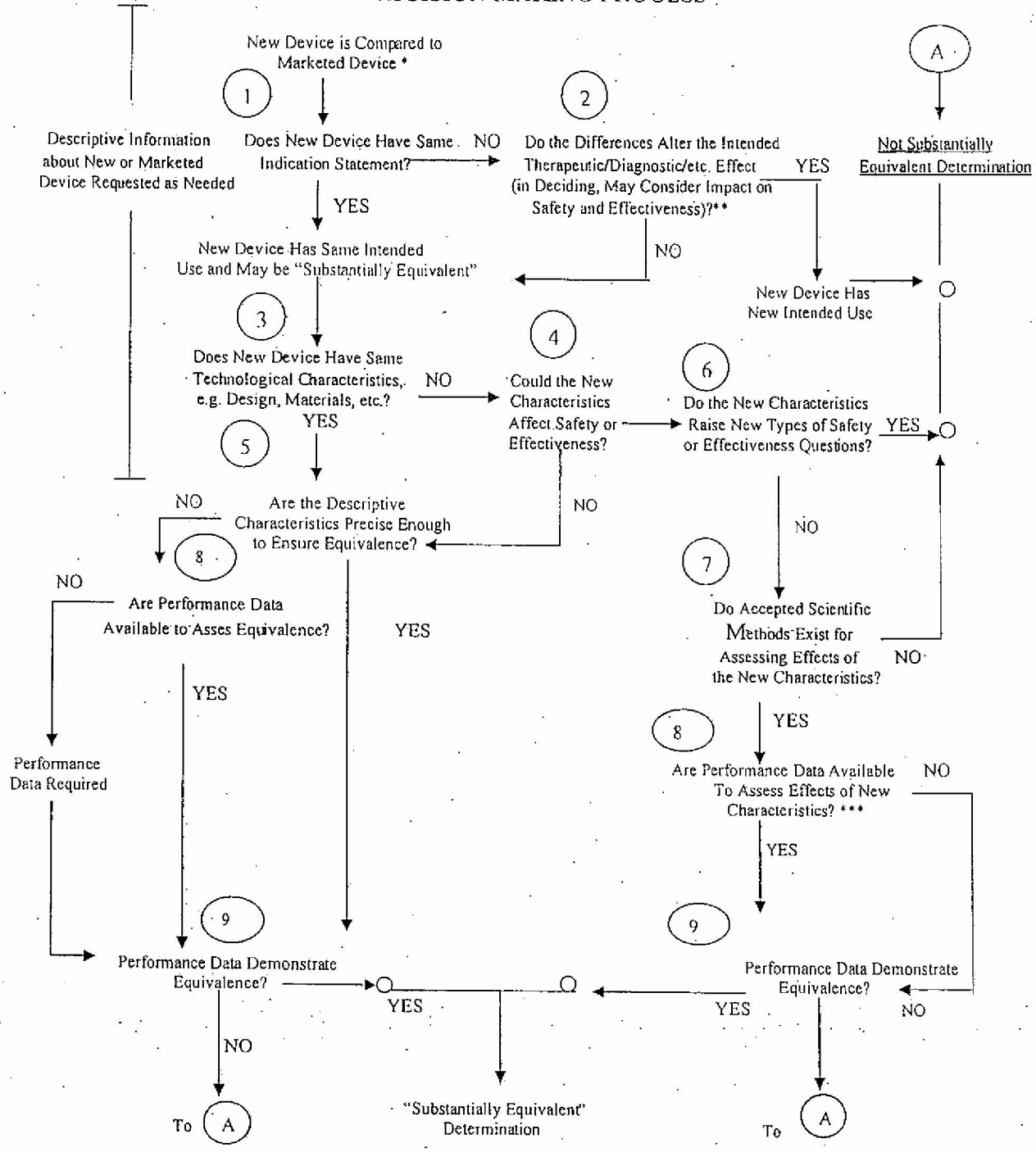
(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: (Branch Chief) (Branch Code) 12/1/11 (Date)

Final Review: for (Division Director) 12/1/11 (Date)

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

109

DEPARTMENT OF HEALTH AND HUMAN SERVICES **M E M O R A N D U M**

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Premarket Notification [510(k)] Review
Traditional/Abbreviated

K113246

Date: December 1, 2011

To: The Record Office: ODE

From: Lauren Giles, Biomedical Engineering Division: DAGID

510(k) Holder: NIBEC Co., Ltd., of Chungcheongbuk-do, Korea

Device Name: *OCS-B* (K113246)

Contact: Mr. Daniel Nam

Phone: 1-213-626-1544

Fax: 1-213-626-1548

Email: Pats0433@yahoo.com

I. Purpose and Submission Summary

NIBEC Co., Ltd., of Chungcheongbuk-do, Korea, has submitted a Premarket Notification (510(k)) to introduce into U.S. interstate commerce *OCS-B*, an organic bovine bone filling material. *OCS-B* is a prescription Class II medical device regulated under 21 CFR 872.3930 as a "Bone Grafting Material." The *OCS-B* is listed under product code NPM.

The submission claims substantial equivalence to *BIO-OSS, BIO-OSS BLOCKS and BIO-OSS Collagen* (K033815).

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription)		X	
(Indicate if: OTC)			X
Truthful and Accuracy Statement	X		
Standards Form	X		

M1

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?			
Does the device design use software?		X	
Is the device sterile?			
Is the device reusable (not reprocessed single use) and are "cleaning" instructions included for the end user?		X	

OCS-B is made from natural hydroxyapatite derived from bovine bone. OCS-B is provided in three types: a vial, bowl, or syringe. All three types are supplied as cancellous granules or cortical granules. *OCS-B* is provided sterile under gamma radiation and packaged in Tyvek pouch. *OCS-B* is to be mixed with distilled water or sterile normal saline unless large maxillofacial defects are present, then it should be mixed with autogenous bone in a 1:1 ratio. Listed below is the complete product list.

(b)(4)

IV. Indications for Use

OCS-B® is recommended for:

- Augmentation or reconstructive treatment of the alveolar ridge.
- Filling of infrabony periodontal defects.
- Filling of defects after root resection, apicoectomy, and cystectomy.
- Filling of extraction sockets to enhance preservation of the alveolar ridge.
- Elevation of the maxillary sinus floor.
- Filling of periodontal defects in conjunction with products intend for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR).
- Filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration (GBR).

The IFUS provided in the submission is not marked for prescription use.

V. Deficiencies

(b)(4)

[redacted]

VI. Contact History

On December 1, 2011 applicant was contacted via email and provided with the deficiency listed above and advise the submission will be place on telephone hold.

VII. Recommendation

Telephone Hold.

Reviewer
Lauren M. Giles, B.S. BME
Biomedical Engineer

12/1/2011
Date

Branch Review
M. Susan Runner, D.D.S., M.A.
Branch Chief Dental Devices

12/1/11
Date

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Giles, Lauren

From: Giles, Lauren
Sent: Thursday, December 01, 2011 12:32 PM
To: 'Pats0433@yahoo.com'
Subject: OCS-B (K113246) Additional Information Request and Telephone Hold

Mr. Nam,

I have been assigned to the review of *OCS-B (K113246)*. After review of your submission, I have come across the following deficiency in the submission that should be addressed to facilitate a complete review of your submission:

(b)(4) [redacted]

I am placing this document on telephone hold pending the submission of information in response to these requests and the determination that this information fulfills each request. In order to remove this document from its hold status, you must submit this information in hard copy to the Document Mail Center at the same address to which your original submission was sent. In addition, please send an electronic copy of your response to me via email.

Please contact me with questions or concerns.

Sincerely,

Lauren Giles
Biomedical Engineer/Reviewer
FDA/ODE/DAGID/DEDB
10903 New Hampshire Avenue
WO66 - Rm. 2546
Silver Spring, MD 20993
phone: 301-796-9552
fax: 301-847-8109
Lauren.Giles@fda.hhs.gov

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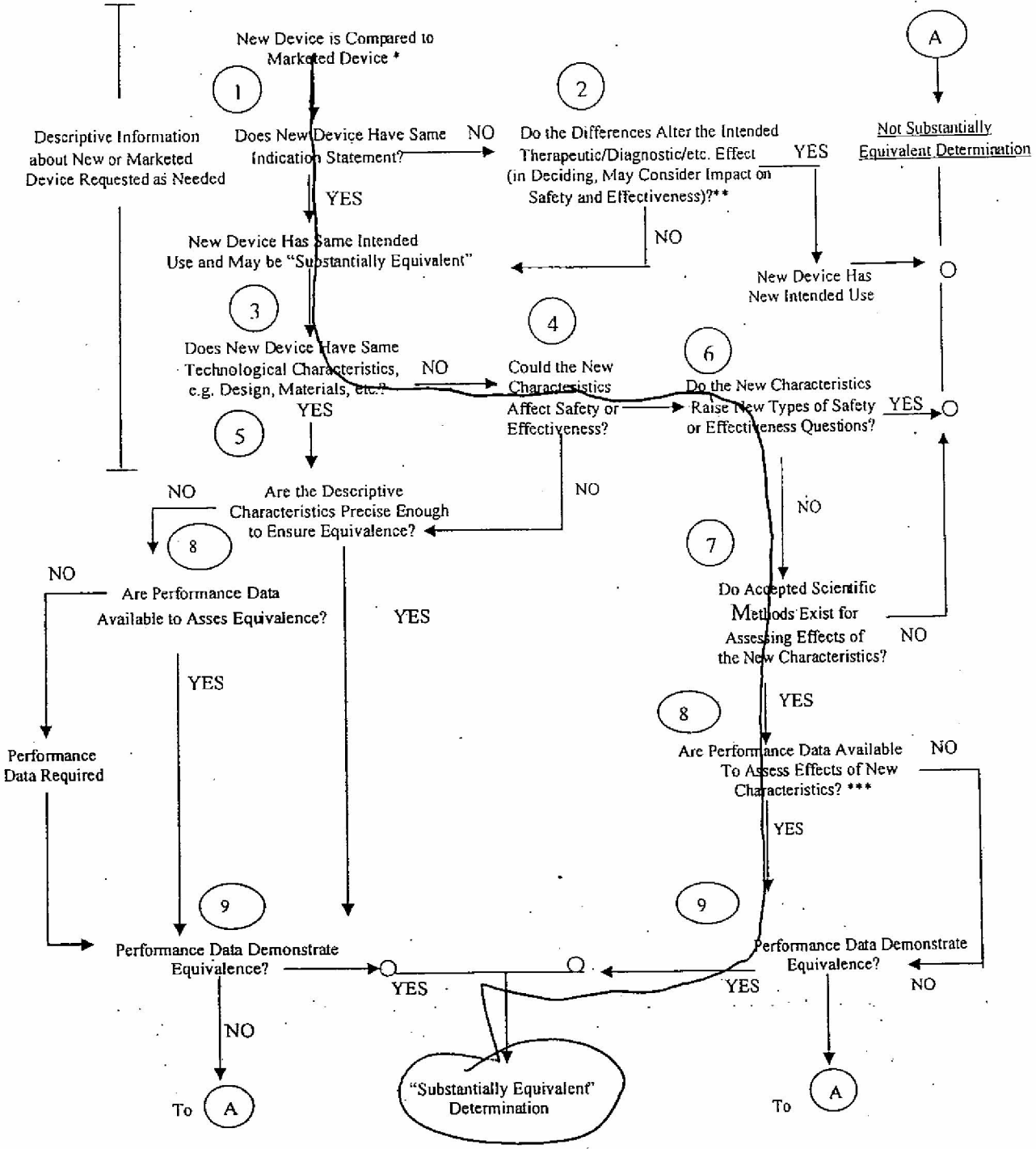
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



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*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

8

DEPARTMENT OF HEALTH & 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

K 113246/S1

May 15, 2012

NIBEC COMPANY, LIMITED
C/O PATS CORP.
4568 W. 1ST STREET
SUITE 104
LOS ANGELES, CALIFORNIA 90004
ATTN: DANIEL NAM

510k Number: K113246

Product: OCS-B

Extended Until: 06/11/2012

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information (AI) is not received by the "Extended Until" date shown above, your premarket notification will be considered withdrawn (21 CFR 807.87(l)). If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

Payne, Melissa T*

From: Microsoft Outlook
To: 'pats0433@yahoo.com'
Sent: Tuesday, May 15, 2012 11:10 AM
Subject: Relayed: K113246 FDA Extension Letter

Delivery to these recipients or distribution lists is complete, but delivery notification was not sent by the destination:

'pats0433@yahoo.com'

Subject: K113246 FDA Extension Letter

Sent by Microsoft Exchange Server 2007

PATS corp.
CERTIFICATION BUSINESS

4568 W. 1st Street, Suite 104
Los Angeles, California, 90004
email: pats0433@yahoo.com
Phone: 213-626-1544 FAX: 213-626-1548

May 4, 2012
Document Mail Center
Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD20993-0002

RE: Request for extension of the revised submission (K113246)

Reference: K113246
Product: OCS-B
Submitter: NIBEC Co., Ltd.
Applicant: PATS CORP
Manufacturer: NIBEC Co., Ltd.

Dear Officer Lauren Giles,

We appreciate your comments on our 510K submission. We have received your letter of requirements regarding the product with the 510K number, **K113246** as shown above. All of your comments are being seriously considered and being reflected in our revised submission. However, the issue of test report to solve several deficiencies you're raised has been delayed than our previous schedule. To this regard, we would like to extend the submission deadline as June 11, 2012.

If you have any question, please feel free to contact me. Thanks.

Best regards,

Daniel Nam (General Manager)
Authorized Agent of 510K Applicant

DEPARTMENT OF HEALTH & 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

April 19, 2012

NIBEC COMPANY, LIMITED
C/O PATS CORP.
4568 W. 1ST STREET
SUITE 104
LOS ANGELES, CALIFORNIA 90004
ATTN: DANIEL NAM

510k Number: K113246

Product: OCS-B

Extended Until: 05/11/2012

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information (AI) is not received by the "Extended Until" date shown above, your premarket notification will be considered withdrawn (21 CFR 807.87(l)). If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

Nichols, Karl *

From: Microsoft Outlook
To: 'PATS0433@YAHOO.COM'
Sent: Thursday, April 19, 2012 5:48 PM
Subject: Relayed: K113246- Extension Letter

Delivery to these recipients or distribution lists is complete, but delivery notification was not sent by the destination:

'PATS0433@YAHOO.COM'

Subject: K113246- Extension Letter

Sent by Microsoft Exchange Server 2007

PATS corp.
CERTIFICATION BUSINESS

4568 W. 1st Street, Suite 104
Los Angeles, California, 90004
email: pats0433@yahoo.com
Phone: 213-626-1544 FAX: 213-626-1548

April 17, 2012
Document Mail Center
Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring. MD20993-0002

RE: Request for extension of the revised submission (K113246)

Reference: K113246
Product: OCS-B
Submitter: NIBEC Co., Ltd.
Applicant: PATS CORP
Manufacturer: NIBEC Co., Ltd.

Dear Officer Lauren Giles,

We appreciate your comments on our 510K submission. We have received your letter of requirements regarding the product with the 510K number, **K113246** as shown above. All of your comments are being seriously considered and being reflected in our revised submission. However, to make our submission more precise and meet your requirements, we would like to have more time to complete. To this regard, we would like to extend the submission deadline as May 11, 2012.

In addition, please be advised that the address of our contact has been changed from 205 S. Broadway, Suite 718, Los Angeles, CA to 4568 W. 1st Street, Suite 104, Los Angeles, CA 90004.

If you have any question, please feel free to contact me. Thanks.

Best regards,

Daniel Nam (General Manager)
Authorized Agent of 510K Applicant

DEPARTMENT OF HEALTH & 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

March 26, 2012

NIBEC COMPANY, LIMITED
C/O PATS CORP.
4568 W. 1ST STREET
SUITE 104
LOS ANGELES, CALIFORNIA 90004
ATTN: DANIEL NAM

510k Number: K113246
Product: OCS-B
On Hold As of 3/23/2012

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

Grayson, Giovanna *

From: Microsoft Outlook
To: 'pats0433@yahoo.com'
Sent: Monday, March 26, 2012 3:37 PM
Subject: Relayed: Hold Letter

Delivery to these recipients or distribution lists is complete, but delivery notification was not sent by the destination:

'pats0433@yahoo.com'

Subject: Hold Letter

Sent by Microsoft Exchange Server 2007

Grayson, Giovanna *

From: Grayson, Giovanna *
Sent: Monday, March 26, 2012 3:37 PM
To: 'pats0433@yahoo.com'
Subject: Hold Letter
Attachments: image002.png

DEPARTMENT OF HEALTH & 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

March 26, 2012
NAM
DANIEL
NIBEC COMPANY, LIMITED
C/O PATS CORP.
4568 W. 1ST STREET
SUITE 104
LOS ANGELES, CALIFORNIA 90004
ATTN: DANIEL NAM

510k Number: K113246

Product: OCS-B

On Hold As of 3/23/2012
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Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Hawon Gale

Subject: 510(k) Number K113246/S1

To: The Record

Please list CTS decision code TH

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☒ Hold (Additional Information or Telephone Hold).

☐ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.)

Not Substantially Equivalent (NSE) Codes

☐	NO	NSE for lack of predicate
☐	NI	NSE for new intended use
☐	NQ	NSE for new technology that raises new questions of safety and effectiveness
☐	NP	NSE for lack of performance data
☐	NM	NSE requires PMA
☐	NS	NSE no response
☐	NH	NSE for another reason

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*		
510(k) Summary /510(k) Statement	*Attach Summary*		
Truthful and Accurate Statement.	*Must be present for a Final Decision*		
Is the device Class III?			
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			
Is clinical data necessary to support the review of this 510(k)?			
For United States-based clinical studies **only**: Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If study was conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			
All Pediatric Patients age<=21			

Neonate/Newborn (Birth to 28 days)
Infant (29 days -< 2 years old)
Child (2 years -< 12 years old)
Adolescent (12 years -< 18 years old)
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)
Nanotechnology
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html) *Contact OC.*

Regulation Number	**Class***	**Product Code**

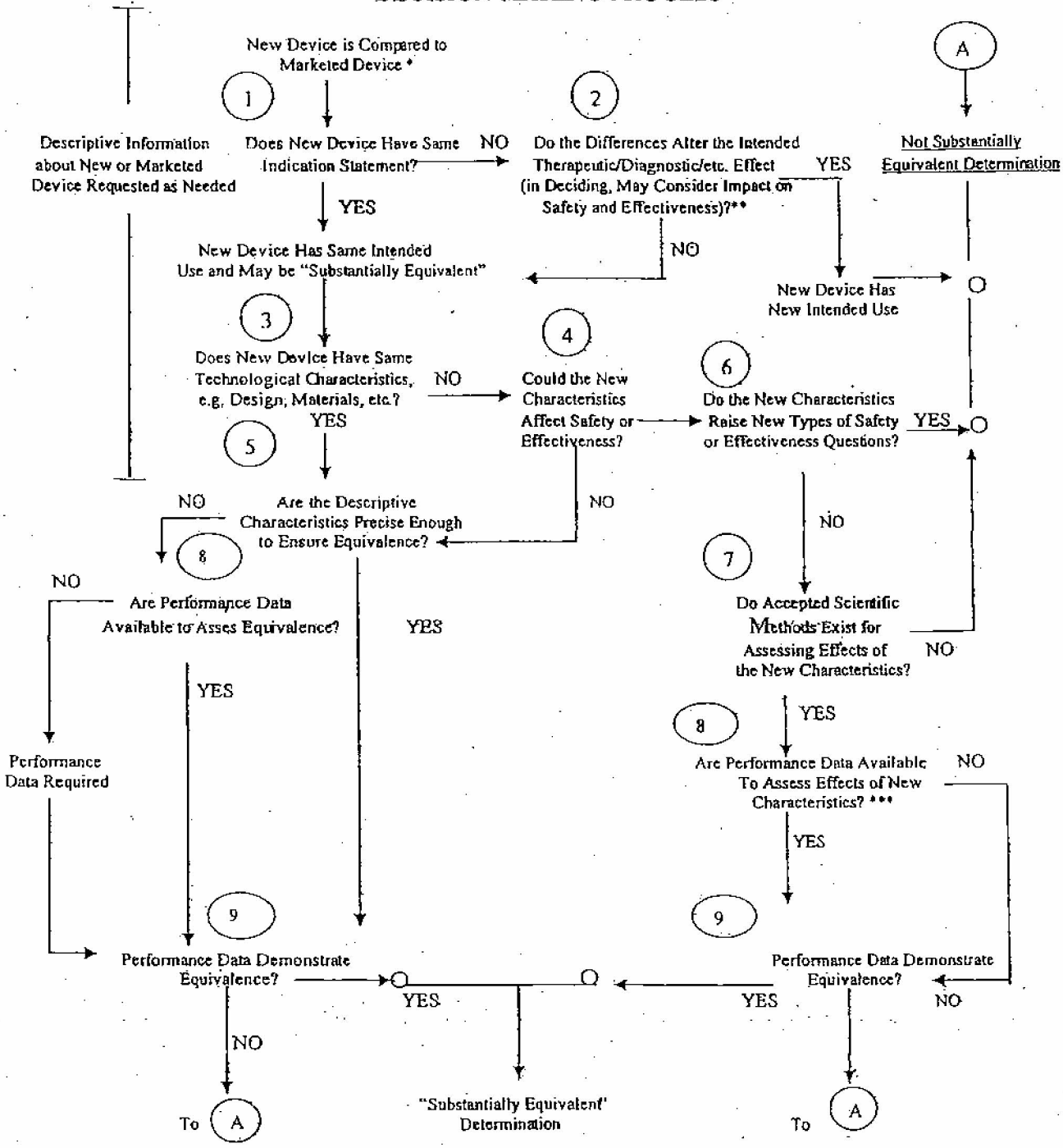
(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: (Branch Chief) (Branch Code) 3/28/12 (Date)

Final Review: (Division Director) 3/23/12 (Date)

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



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** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

DEPARTMENT OF HEALTH AND HUMAN SERVICES **M E M O R A N D U M**

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Premarket Notification [510(k)] Review
Traditional/Abbreviated

Telephone Hold #2

K113246/S001

Date: March 23, 2012

To: The Record Office: ODE

From: Lauren Giles, Biomedical Engineering Division: DAGID

510(k) Holder: NIBEC Co., Ltd., of Chungcheongbuk-do, Korea

Device Name: *OCS-B* (K113246/S001)

Contact: Mr. Daniel Nam

Phone: 1-213-626-1544

Fax: 1-213-626-1548

Email: Pats0433@yahoo.com

I. Purpose and Submission Summary

NIBEC Co., Ltd., of Chungcheongbuk-do, Korea, has submitted a Premarket Notification (510(k)) to introduce into U.S. interstate commerce *OCS-B*, an organic bovine bone filling material. *OCS-B* is a prescription Class II medical device regulated under 21 CFR 872.3930 as a "Bone Grafting Material." The *OCS-B* is listed under product code NPM.

The submission for *OCS-B* consists of Form FDA 3674, Form FDA 3514, 510(k) Cover Letter, Truthful and Accurate Statement, Indication for Use, Safety and Effectiveness Statement, Screen Checklist, FDA Form 3674, Form 3654, Label and Package, User Manual, Product Description, Sterility Validation Report, Substantial Equivalence Report, Biocompatibility and Performance Test report, Risk Analysis Report, Clinical data, 510(k) Summary, Viral Inactivation report.

The primary mode of action for this device is grafting to dental defect to promote bone growth. The submission claims substantial equivalence to *BIO-OSS, BIO-OSS BLOCKS and BIO-OSS Collagen* (K033815).

The submission references the following standards in Form FDA 3514 but has provided Form FDA 3654 for all standards referenced.

Standard	Standard Title	Version
IEC 980	Graphical symbols for use in labeling of medical devices	2003
IEC 1041	Information supplied by the manufacturer with medical devices	1998
ISO 10993-1	Biological evaluation of medical devices – Part 1: Evaluation and Testing	2003
ISO 10993-5	Biological evaluation of medical devices – Part 5: Test for In Vitro Cytotoxicity	
ISO 10993-10	Biological evaluation of medical devices – Part 10: Test for irritation and delayed-type hypersensitivity	2002
ISO 10093-11	Biological evaluation of medical devices – Part 11: Test for system toxicity	2002
ISO 10093-6	Biological evaluation of medical devices – Part 6: Test for local effects after implantation	2007
ISO 14971	Medical Devices – Application of risk management to medical devices	2007

Reviewer's Notes:

- *In Form FDA 3514 the applicant lists the device classification as unknown; in addition on page 52 of the submission the applicant lists the device classification as Class III. However, under the NPM product code, the proposed device is consider Class II and contains special controls and FDA issued guidance document for "Dental Bone Grafting Material" and "Medical Devices Containing Materials Derived for Animal Sources."*
- *Form FDA 3654 has not provided for all the standards listed in Form FDA 3514. In addition, the submission references to several other standards on page 52 of the submission and in the sterilization and performance testing reports. Form FDA 3654 should be provided for all standard referenced or relied on in this submission.*

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription) (Indicate if: OTC)			
Truthful and Accuracy Statement			
Standards Form			

	YES	NO	N/A
Required Elements for 510(k) Summary (21 CFR 807.92)			
Clearly labeled "510(k) Summary"	X		
Submitter' s name, address, phone #, a contact person		X	
Date the summary was prepared		X	

			YES	NO	N/A
	The name of the device/trade name/common name/classification name			X	
	An identification of the legally marketed Predicate		X		
	Description of the subject device			X	
	Statement of intended use(identical to indications for use)		X		
	Technological	if same, a summary of comparison of technological characters		X	
		If different, a summary of how do they compare to the Predicate		X	
	Performance Data	Brief discussion of non-clinical data submitted, referenced, or relied on		X	
		Brief discussion of clinical data submitted, referenced, or relied on, including: ▪ Description upon whom the device was tested, ▪ Data obtained from the tests and especially: ▪ Adverse events and complications ▪ Other information for SE determination		X	
		Conclusion that data demonstrate SE		X	
Required Elements for 510(k) Statement (21 CFR 807.93)					
	Signed verbatim statement		X		

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?	X		
Does the device design use software?		X	
Is the device sterile?	X		
Is the device reusable (not reprocessed single use) and are "cleaning" instructions included for the end user?		X	

OSC-B is an anorganic xenogeneic bone grafting material. *OSC-B* is composed of bovine natural hydroxyapatite derived for Korean native cattle bone. OCS-B is provided in three

types: a vial, bowl, or syringe. All three types are supplied as cancellous granules or cortical granules. The particle size of *OSC-B* ranges from 0.212mm to 2.0mm. The Ca/P ratio of *OCS-B* is 1.66.

The device description includes a step-by-step flow chart and narrative of the manufacturing process for *OSC-B*. (b)(4)

(b)(4)

Reviewer's Notes:

- *Korea is not listed on the FDA guidance document for "Medical Devices Containing Material Derived from Animal Source" as a country which BSE exist or presents a significant risk.*
- *The submission does not include any details on the chemical composition by weight or molar weight for the proposed device. In addition no details can be found on the raising, feeding, vaccination of the cattle.*
- *The submission does not specify the protein assay and what proteins are being tested.*

IV. Indications for Use

OCS-B® is recommended for:

- Augmentation or reconstructive treatment of the alveolar ridge.
- Filling of infrabony periodontal defects.
- Filling of defects after root resection, apicoectomy, and cystectomy.
- Filling of extraction sockets to enhance preservation of the alveolar ridge.
- Elevation of the maxillary sinus floor.
- Filling of periodontal defects in conjunction with products intend for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR).
- Filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration (GBR).

Reviewer's Notes:
The IFUS provided in the submission is not marked for prescription use. The IFUS is identical in wording and content to the declared predicate device.

V. Labeling

The submission includes draft labeling for the packaging and also contains draft Instructions

for Use.

The *OCS-B* products contain several packaging labels including a Tyvek label, paper box, and outer carton box. The labeling include a product description (trade name, particle size, granule type, and weight), the manufacturer information, sterile, single use only, caution to read instructions, lot and expiration date, and the prescription statement as required by 21 CFR 801.109. The labeling contains no symbols and all text is written in the English language.

The submission also includes draft Instructions for Use. The main insert state that *OCS-B* should only be placed in well vascularized bone. *OCS-B* can be mixed with autogenous bone, osseous coagulum, patient's blood or sterile normal saline. For larger defects it should be mixed with autogenous bone in a 1:1 ratio. *OCS-B* should be placed with light/moderate pressure and the defects should not be overfilled. The instructions state the graft site should be allowed to heal for 6 months prior to implant placement.

In addition to the main insert, each type (vial, bowl, and syringe) of *OCS-B* contains directions. These direction include sections for Components and Characteristics, Uses, Instructions, Contraindications, Adverse Reactions, How Supplied, and Storage. The Instructions are similar to that in the main insert. The proposed device is contraindicated for use in people with metabolic diseases, liver disease, and vascular impairment among others. The "How Supplied" section details the all the variations of the granule, weight, and size of *OCS-B* provided for each type (vial, bowl, and syringe). *OCS-B* is to be stored at room temperature.

Reviewer's Notes:

- *The "Components and Characteristics" sections of the directions contain the following unsubstantiated claims:*
  - *"OCS-B is free of organic impurities including inflammatory proteins, lipid, and provides similar nanocrystal structure to human bone."*
  - *"OCS-B facilitates osteoconduction due to its 3-dimensional porous structure and helps mineralization process."*
- *The Uses section should be revised to state "Intended Use." The Intended Use should be identical to the Indications for Use Statement provided in the submission.*
- *The "Instructions" sections of the directions contain the following unsubstantiated claims:*
  - *"Mixing OCS-B cancellous granules and OCS-B cortical granules in a ratio of 1:1 in bone regeneration procedure may result in elevating the strength of new bone."*

VI. Sterilization/Shelf Life/Reuse

OSC-B is provided sterile. *OSC-B* is sterilized to a (b)(4) by gamma radiation at a dosage of (b)(4) according to ISO 11137-1 and -2 using a microbiological method. Sterilization validation reports were provided for the vial, bowl and syringe type.

The submission includes a detailed description of the packaging of the *OCS-B*. *OCS-B* is provided in a vial, bowl, or syringe. The vial is sealed by a rubber cap while the bowl and syringe type are sealed with sheet.

Content	Container	Component	Specification

OCS-B, K113246, NIBEC Co., Ltd.

OCS-B	Vial package	Glass Rubber	5ml Vial OP
OCS-B	Bowl type	Glass PS sheet	Octadon polystyrene
OCS-B	Syringe type	COC Rubber A push stick CAP	Topas - PP PP

Each type of *OSC-B* is packaged in a blister made of PET and Tyvek and placed in a inner and outer carton box for shipping. Once the product is opened it is not to be re-sterilized or reused.

An expiration date of 3 years from manufacture was determined by accelerated testing by verifying the indicated weight. The weight, particle size, and pH were measured at an accelerated rate date of 0, 1.5 and 3 years. For the accelerated testing, a temperature of 68°C and humidity of 60% where utilized as the parameters. Accelerated aging test was conducted according to ASTM F-1980-99.

VII. Biocompatibility

Biocompatibility Testing According to ISO 10993-1:
In accordance with the Blue Book Guidance G95-1, ("Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing"), acceptable test results should be supplied for the biological tests for cytotoxicity, sensitization, irritation, acute/subchronic/chronic toxicity, genotoxicity, implantation, and carcinogenicity (only if positive genotoxicity). Below is a summary of the testing provided in the submission:

Intracutaneous Reactivity Test (irritation): Animal intradermal reactivity test was conducted according to ISO 10993-10 since the proposed device is classified as an implanted material. The test sample was prepared according to ISO 10993-12. (b)(4)

(b)(4)

Implantation Test: The report states that implantation testing was conducted according to ISO 10993-6 for a period of 12 weeks (3 months). According to the standard, for degradable/absorbable materials the tissue response should be evaluated based on the degradation process. (b)(4)

(b)(4) *OCS-B* implantation testing was conducted in comparison to Bio-OSS® as a reference material. (b)(4)

(b)(4)

(b)(4)

Acute Systemic Toxicity Test: The report states that the testing for acute systemic toxicity was conducted according to ISO 10993-11. (b)(4)

(b)(4)

Pyrogen Test (rabbit and LAL testing required)*: Three, male New Zealand White Rabbits were intravenously injected in the ear with 10ml/kg of the test substance. (b)(4)

(b)(4)

Mutation (AMES Test): **The English translated report in incomplete. The protocol contains only a brief summary and the charts for the results are blank.**

Maximization Test (sensitization test): The test report states a guinea pig maximization test was conducted according to ISO 10993-10. (b)(4)

(b)(4)

Cytotoxicity Test: The report states that cytotoxicity testing was conducted according to ISO 10993-5. (b)(4)

(b)(4)

(b)(4) The test article is considered non-cytotoxic as defined in ISO 10993-5 since none of the cultures had a grade greater than 2.

Reviewer's Notes:

- *The submission includes an analysis of the biocompatibility of the proposed device. However based on the classification of the proposed device the applicant should include the following additional biocompatibility data:*
  - *Genotoxicity*
  - *LAL Testing*
  - *Chronic Toxicity*
- *The submission does not include any data to quantify the quality and type of bone that has formed. The applicant should provide the resorption rate for the proposed device and the solubility at different temperature and solution medium.*

Viral Safety Evaluation: Please see attached consult review by Peter Hudson.

VIII. Software

OSC-B does not appear to contain any software as defined in the scope of FDA's "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". Therefore, software documentation and validation is not required for *OSC-B*.

IX. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

OSC-B does not appear to produce an EM field, utilize electricity, or produce a thermal effect. Therefore, EMC, electrical safety, and thermal safety are not applicable.

X. Performance Testing – Bench

(b)(4)

[redacted]

(b)(4)

(b)(4)

(b)(4)

(b)(4)

[redacted]

Reviewer's Notes:

- *The determination of low crystallinity was determined by SEM image analysis in comparison to a reference device and the declared predicate. The submission states the particles are spherical in shape. Resportion rate increases as the crystallinity of HA decreases. Crystallinity is highly dependence on the sintering temperature. The higher the sintering temperature the more crystalline the HA.*

XI. Performance Testing – Animal

Section 7 of the submission includes a clinical evaluation of the proposed device. Included in the clinical evaluation in section 7.2.3 and Annex 7-3 is an Animal Study for *OCS-B*. (b)(4)

(b)(4)

[redacted]

(b)(4)

[redacted]

XII. Performance Testing – Clinical

(b)(4)

[redacted]

XIII. Predicate Device Comparison

The submission claims substantial equivalence to *BIO-OSS, BIO-OSS BLOCKS and BIO-OSS Collagen* (K033815). However, this is a special for change in the cattle source to Australian cows. The original *BIO-OSS*, an anorganic bovine bone, was cleared in K871773.

XIV. Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?			If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
3. Same Technological Characteristics?			If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?			If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
8. Performance Data Available?			If **NO** = Request Data
9. Data Demonstrate Equivalence?			Final Decision:

Note: See http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:
2. Explain why there is or is not a new effect or safety or effectiveness issue:
3. Describe the new technological characteristics:
4. Explain how new characteristics could or could not affect safety or effectiveness:
5. Explain how descriptive characteristics are not precise enough:
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
7. Explain why existing scientific methods can not be used:
8. Explain what performance data is needed:
9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

XV. Deficiencies

(b)(4) [redacted]

(b)(4)

(b)(4)

(b)(4)

(b)(4)

[redacted]

XVI. Contact History

11/2/11 – Original Submission Recieved

12/1/11 – TH1: On December 1, 2011 applicant was contacted via email and provided with the deficiency listed on the same date and advise the submission will be place on telephone hold.

3/23/12 – TH2: On March 23, 2012 applicant was contacted via email and provided with the deficiency listed for the same date and advise the submission will be place on telephone hold.

XVII. Recommendation

Telephone Hold.

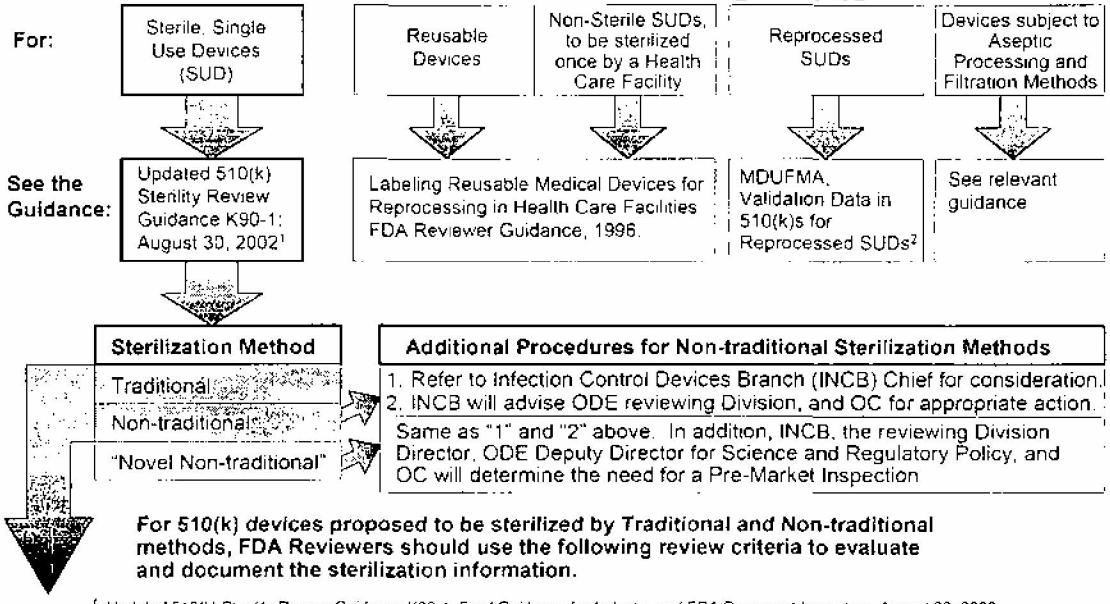
Reviewer
Lauren Giles, B.S. BME
Biomedical Engineer

Date 3/23/12

Branch Review
M. Susan Runner, D.D.S., M.A.
Branch Chief Dental Devices

Date 3/23/12

Sterile Devices in Premarket Notification [510(k)] Submissions



[1] *Updated 510(k) Sterility Review Guidance K90-1, Final Guidance for Industry and FDA Document Issued on, August 30, 2002*
[2] *Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single Use Devices*

1. Sterilant:	YES	NO
a. **Sterilization method** description (e.g., Steam, EtO, Radiation):	Gamma Radiation	
b. **Dose**, for radiation (e.g., 25 – 40 kGy):	25kGy	
c. **Sterilant residuals** remaining on the device:	N/A	

For EO, the maximum levels of residuals of EO and ethylene chlorhydrin that remain on the device (note: not to include ethylene glycol residual level because the recognized standard, "ANSI/AAMI/ISO 10993-7:1995 Biological *Evaluation of Medical Devices – Part 7: Ethylene Oxide sterilization* residuals," does not include measurement of ethylene glycol residuals);	
2. A description of the Validation Method for the sterilization cycle (not data): (Citation of an FDA recognized standard is acceptable (e.g., ANSI/AAMI/ISO 11135))	ISO 11137-1,-2 VDMax
3. Sterility assurance level (SAL): (e.g., 10^{-6} for all devices (except 10^{-3} for devices that contact intact skin))	10^{-6}
4. Is it labeled "Pyrogen Free"? If so, a description of the method: (e.g., LAL (*Limulus* Amebocyte Lysate test))	??
5. A description of the packaging (not including package integrity test data):	See memo Sec. VI

MEMO TO THE RECORD

K113246 Consult

DATE: 3/23/12
OFFICE: HFZ-410
DIVISION: DSORD/PRSB
FROM: Biologist
RE: Animal husbandry and viral inactivation review
CONSULT TO: Ms. Lauren Giles

Recommendation: The information provided regarding the animal husbandry, manufacturing and viral inactivation validation lacks some detail. Two deficiencies are identified at the end of the review memo – additional information is recommended. The viral inactivation validation is significantly robust.

Review:
Ms. Giles has requested a consult review regarding the animal husbandry and viral inactivation information of premarket notification K113246:

Hi Peter,

Thanks you for stopping by earlier today to discuss this submission. I would like you get your opinion on the validity of the animal inspection certificate, viral inactivation report, and TSE report. The file, K113246, has been uploaded on image. The report can be found on the following pages.

---Animal Inspection Certificate: 66 and 68 (Section 5.3 of the risk analysis contains addition info starting on pg. 619)
---Manufacturing Process: pg. 106-111
---Viral Inactivation Report: pg. 987-1011
---TSE report: The TSE Inactivation Report begins on page 1026; however, the English protocol report begins is on page 1059-1097 and the English final report begins on page 1111.

Please let me know if you need any additional information.

Thanks again

Lauren Giles
FDA/ODE/DAGID/DEDB
phone: 301-796-9552

NIBEC Co., Ltd. has submitted a premarket notification regarding their bone grafting device, OCS-B. NIBEC is in South Korea. The product is identified as bone filling material.

Indications for Use

Indications for Use:

OCS-B is intended for use in dental surgery.
The products may be used in surgical procedures such as:

* Augmentation or reconstructive treatment of alveolar ridge
* Filling of periodontal defects
* Filling of defects after root resection, apicocectomy, and cystectomy
* Filling of extraction sockets to enhance preservation of the alveolar ridge
* Elevation of maxillary sinus floor
* Filling of periodontal defects in conjunction with products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR)
* Filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration

Device description

The product is described as consisting of "natural hydroxyapatite" derived from bovine bone. The sponsor asserts that "organic material is efficiently removed and does not show immune reaction". The sponsor also asserts that the bone is not contaminated with BSE.

Animal husbandry

Within the sponsor's risk analysis, section 5.3, Identification of characteristics related with the safety of medical device, the sponsor provided the following information:

- The bone graft material is made from bovine bone (*Bos Taurus coreana*, castrated animals) – specifically the thigh or femur bone
- The bone is obtained from cattle that are 3-7 years of age; the animals have been bred on Jelu island
- The animals are inspected by veterinarians

The sponsor provides an inspector/seal indication for their veterinary surgeon, Dr. Sung Hun Kim, Gangwon-do South Branch Veterinary Laboratory of Stock Epidemics Prevention and Sanitary. The sponsor may have the required animal husbandry information but they've either not provided it completely or it is within a section of the 510(k) I have not reviewed. I did go through their entire Risk Analysis.

Deficiency

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

[redacted]

Peter L. Hudson, Ph.D./Reviewer (Date)
Division of General and Restorative Devices
Plastic and Reconstructive Surgery Branch

Giles, Lauren

From: Giles, Lauren
Sent: Friday, March 23, 2012 4:27 PM
To: 'Gilltaik Gong'
Subject: OCS-B (K113246) Additional Information Request and Telephone Hold

Mr. Nam,

I have been assigned to the review of *OCS-B (K113246)*. After initial review of your submission, I have come across the following deficiency in the submission that should be addressed.

(b)(4)

(b)(4)

(b)(4)

[redacted]

I am placing this document on telephone hold pending the submission of information in response to these requests and the determination that this information fulfills each request. In order to remove this document

from its hold status, you must submit this information in hard copy to the Document Mail Center at the same address to which your original submission was sent. In addition, please send an electronic copy of your response to me via email. I am available to review any information you are considering before its official submission in order to ensure that it fulfills these requests.

Please contact me with questions or concerns.

Sincerely,

Lauren Giles
Biomedical Engineer/Reviewer
FDA/ODE/DAGID/DEDB
10903 New Hampshire Avenue
WO66 - Rm. 2546
Silver Spring, MD 20993
phone: 301-796-9552
fax: 301-847-8109
Lauren.Giles@fda.hhs.gov

DEPARTMENT OF HEALTH & 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

February 01, 2012

NIBEC COMPANY, LIMITED
C/O PATS CORP.
4568 W. 1ST STREET
SUITE 104
LOS ANGELES, CALIFORNIA 90004
ATTN: DANIEL NAM

510k Number: K113246

Product: OCS-B

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

Grayson, Giovanna *

From: Microsoft Outlook
To: 'pats0433@yahoo.com'
Sent: Wednesday, February 01, 2012 1:22 PM
Subject: Relayed: ack letter

Delivery to these recipients or distribution lists is complete, but delivery notification was not sent by the destination:

'pats0433@yahoo.com'

Subject: ack letter

Sent by Microsoft Exchange Server 2007

Grayson, Giovanna *

From: Grayson, Giovanna *
Sent: Wednesday, February 01, 2012 1:22 PM
To: 'pats0433@yahoo.com'
Subject: ack letter
Attachments: image002.png

DEPARTMENT OF HEALTH & 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

February 01, 2012

NAM
DANIEL
NIBEC COMPANY, LIMITED
C/O PATS CORP.
4568 W. 1ST STREET
SUITE 104
LOS ANGELES, CALIFORNIA 90004
ATTN: DANIEL NAM

510k Number: K113246

Product: OCS-B

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510 (k).

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If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

K7

PATS corp.
CERTIFICATION BUSINESS

4568 W. 1st Street, Suite 104
Los Angeles, CA 90004
Tel: +1 213 626 1544
Fax: +1 213 626 1548

Jan. 09. 2012
Document Mail Center
Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring. MD20993-0002

Reference : K113246
Product: OCS-B
Submitter: **Nibec co ltd**
Applicant: PATS CORP
Manufacturer: **Nibec co ltd**

Dear Officer

We got the letter of your requirements regarding the product (**K113246**).
According to your requests. we hereby submit the additional information of your requests.
Please check the following.
Thank you.

Table of Contents

1. AI request letter answer sheet
2. Sterilization test report (Syringe, Vial, Bowl)
3. Test Reports

Very truly yours,

Mr. Daniel Nam / General Manager
Authorized Agent for 510K Applicant.

Answer sheet

The submission includes Sterility Validation Report, Biocompatibility Test Report, and Performance Test Report for review by the FDA. However, the reports appear not to be completely translated into English. Portions of the content, charts and graphs are not written in the English language. It is difficult to discern which reports have been translated. To facilitate a complete and through review of your submission please provide revised documentation of which the contents, charts, and graphs are completely translated into English. Please remove/delete all foreign language to only include the English translated copy.

>>>> As your request, Modified and translated to English language. But It is hard to remove the all other language therefore we cannot delete the other language also it is certified report form of report already have been reviewed without problem.
Please check and start to review with this documents.

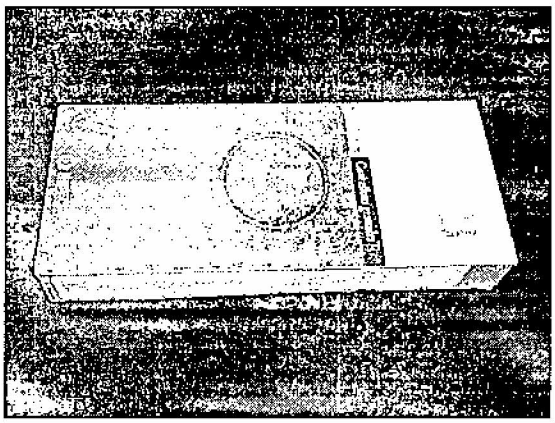
NIBEC

(b)(4)

의료기기에 대한 감마 멸균 유효성 확인 평가

Gamma Sterilization Validation for the Medical Device

Product : OCS-B



(b)(4)

제조업체(Manufacturer)

(주)나이벡

NIBEC

충청북도 진천군 이월면 신월리
1127 번지 이월전기전자농공단지
1127, Iwol electric industrial Complex,
Sinwol-ri, Iwol-myeon, Jincheon-gun,
Chungcheongbuk-do, 365-824, Korea
Tel. +82-2-740-8757

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NIBEC

Report No. 101005-1

의료기기에 대한 감마 멸균 유효성 확인 평가
Gamma Sterilization Validation for the Medical Device

Product : Bone graft material(OCS-B)

멸균전문업체(Contract Sterilizer)
그린피아 기술(주)
GREENPIA TECH. INC.

경기도 여주군 능서면 신지리 329

329 Shingi-ri, Neungseo-myun, Yeoju,
Gyeonggi-do, 469-810, Korea
Tel. : +82-31-882-5366

제조업체(Manufacturer)
(주)나이벡
NIBEC

충청북도 진천군 이월면 신월리
1127 번지 이월전기전자농공단지
1127, Iwol electric industrial Complex,
Sinwol-ri, Iwol-myeon, Jincheon-gun,
Chungcheongbuk-do, 365-824, Korea
Tel.: +82-43-532-7458

NIBEC

Report No. 101005-1

의료기기에 대한 감마 멸균 유효성 확인 평가

Gamma Sterilization Validation for the Medical Device

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Attachment 17

검증선량에 대한 무균성 시험

Test of Sterility for the Verification Dose

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Attachment 18

멸균선량 결정을 위한 테이블

Table for Determination of the sterilization dose

ISO 11137 VDmax 25 Method

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Attachment 21

사이클 타이머 교정성적서
Certificate of Calibration

Calibration item :
EAGLE SIGNAL TIMER

(Setting time for irradiation)

(b)(4)

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Attachment 22

선량 측정 시스템 교정 성적서
Certificate of Dosimetry system

Calibration item :

1. Spectrophotometer

Calibration institute :

(b)(4) [redacted]

2. Thickness gauge

Calibration institute :

(b)(4) [redacted]

by (b)(4) [redacted]

3. Routine Dosimeters

Calibration institute :

(b)(4) [redacted]

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Attachment 23

설비의 선량분포도
Installation Dose Mapping

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NIBEC

Report No. (b)(4)

의료기기에 대한 감마 멸균 유효성 확인 평가

Gamma Sterilization Validation for the Medical Device

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첨부(Attachment) 7

검증선량 측정 보고서
Dosimetry Report for Verification Dose

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첨부(Attachment) 8

검증선량에 대한 무균성 시험
Test of Sterility for the Verification Dose

(b)(4)

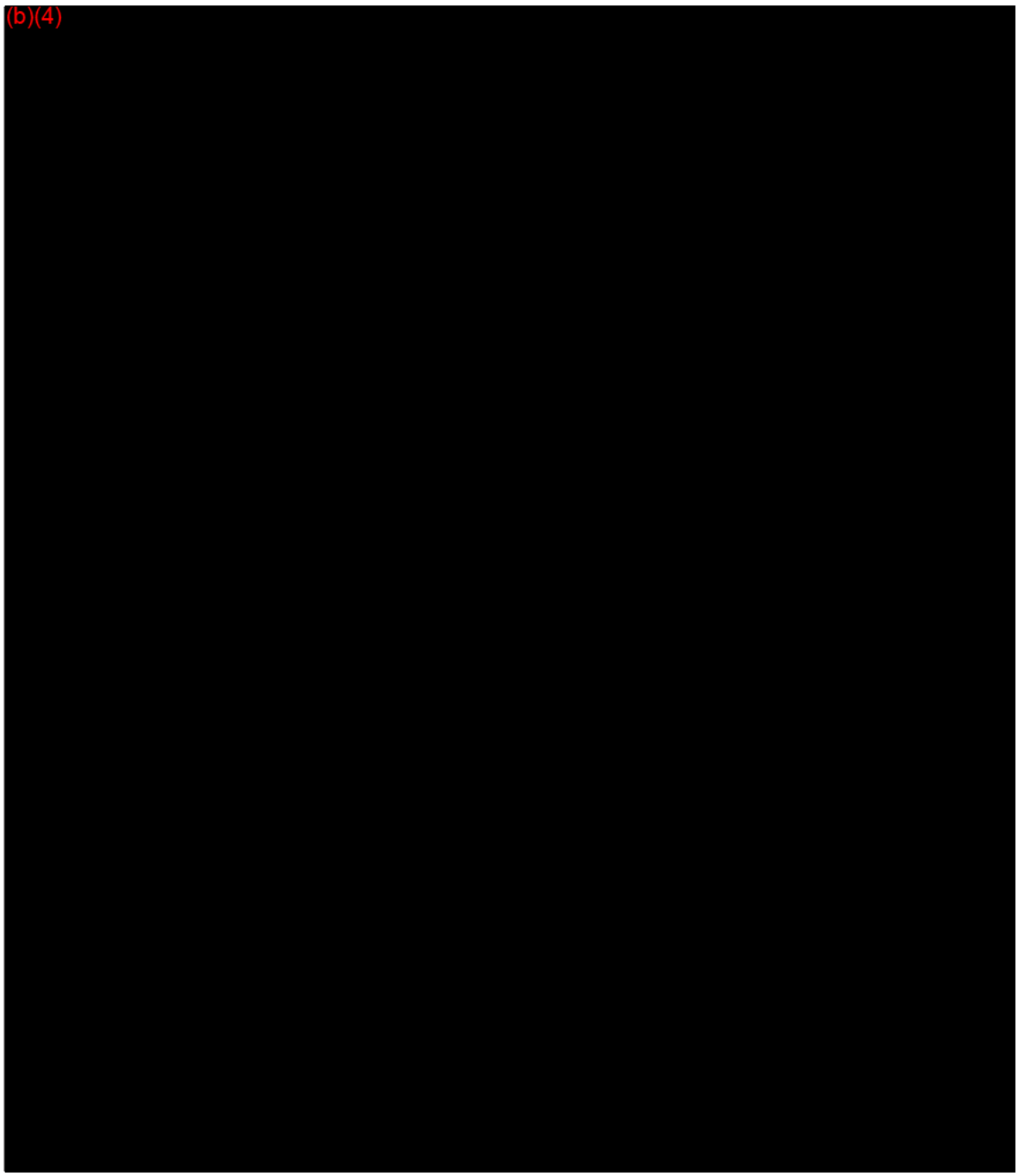
첨부(Attachment) 9

멸균선량 결정을 위한 테이블

Table for Determination of the sterilization dose

ISO 11137 VDmax 25 Method

(b)(4)



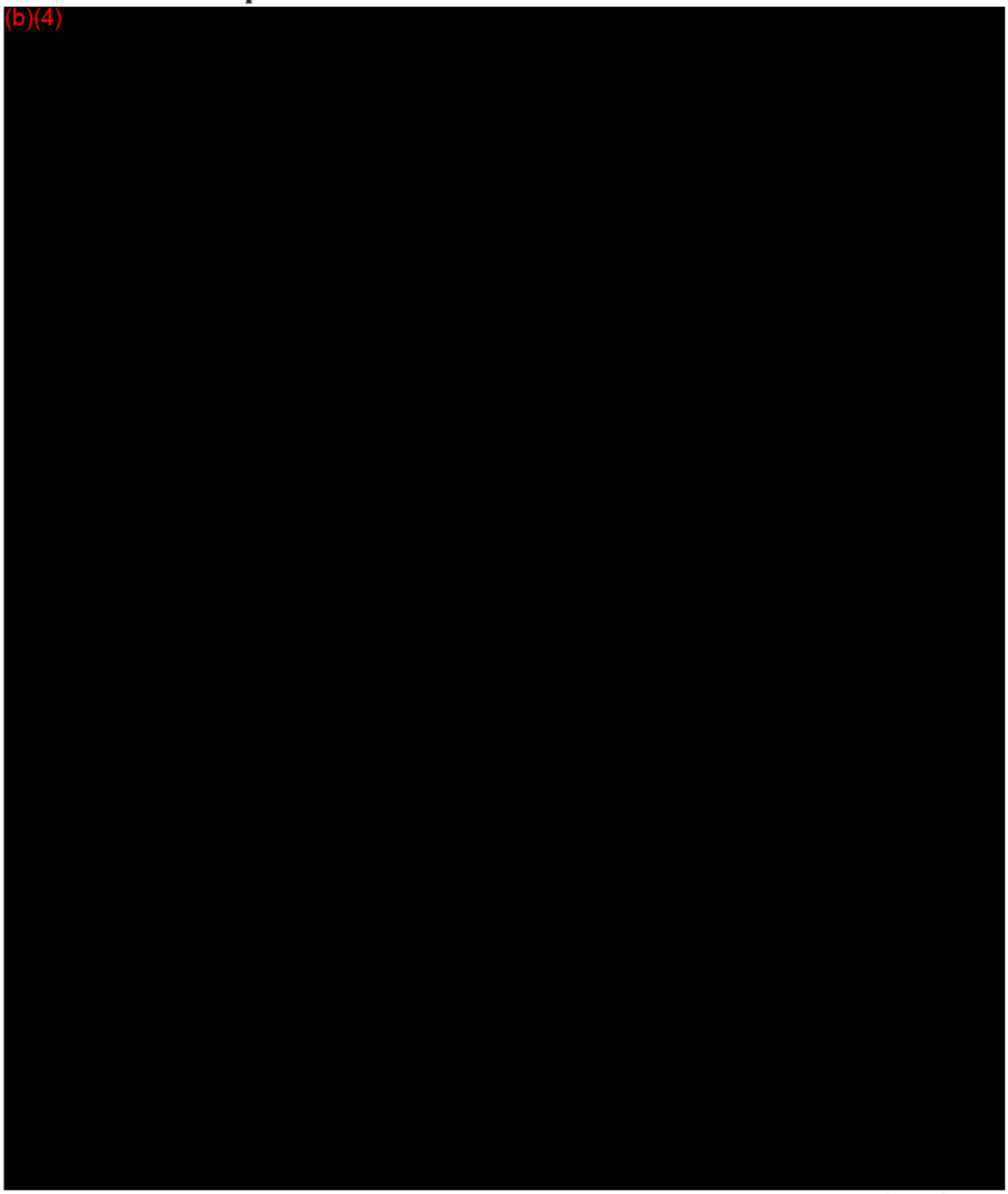
(b)(4)

첨부(Attachment) 10

방사선 안정 재질의 사례

Examples of radiation stable materials

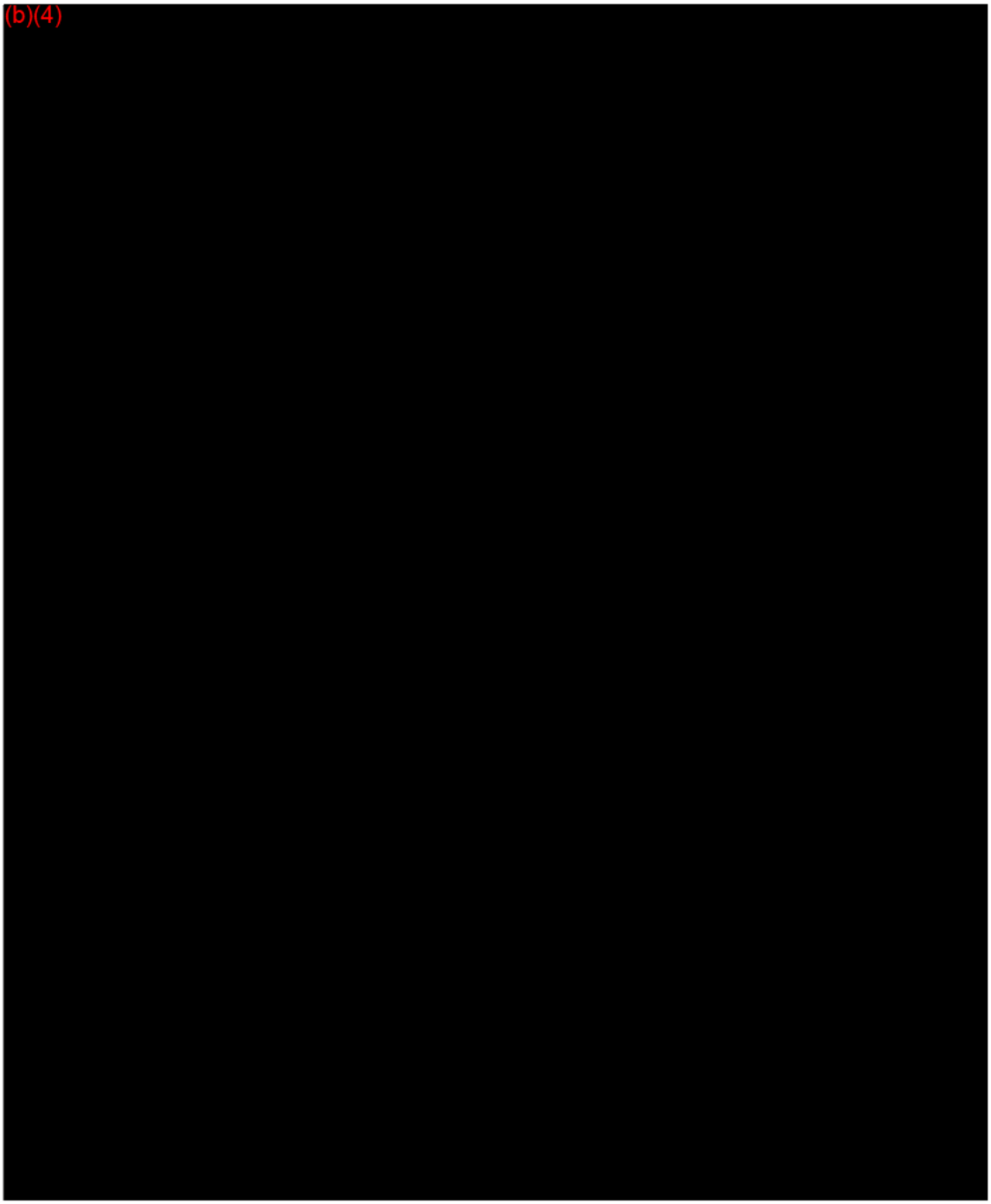
(b)(4)



Source : ISO 11137(2003)

첨부(Attachment) 11

제품 적재 형태
Product Loading Pattern



첨부(Attachment) 12

조사용 운송 용기

Irradiation Container

(b)(4)

첨부(Attachment) 13

제품의 선량 분포도

Product Dose Mapping

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첨부(Attachment) 17

감마선 조사기 체계

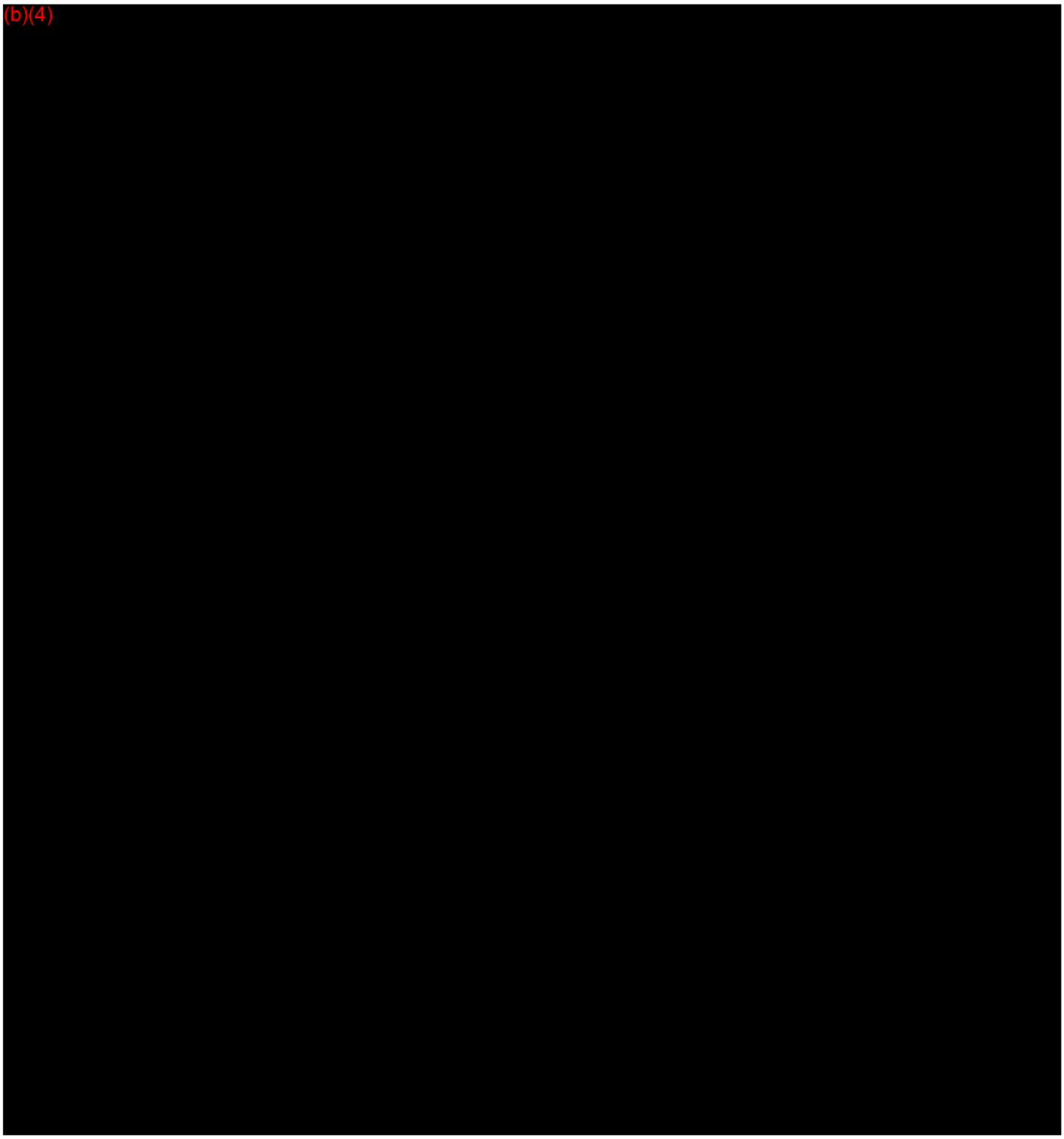
Scheme of gamma irradiator IS8900

(b)(4)

첨부(Attachment) 18

선원 판넬 및 캡슐
Source Panel and Capsule

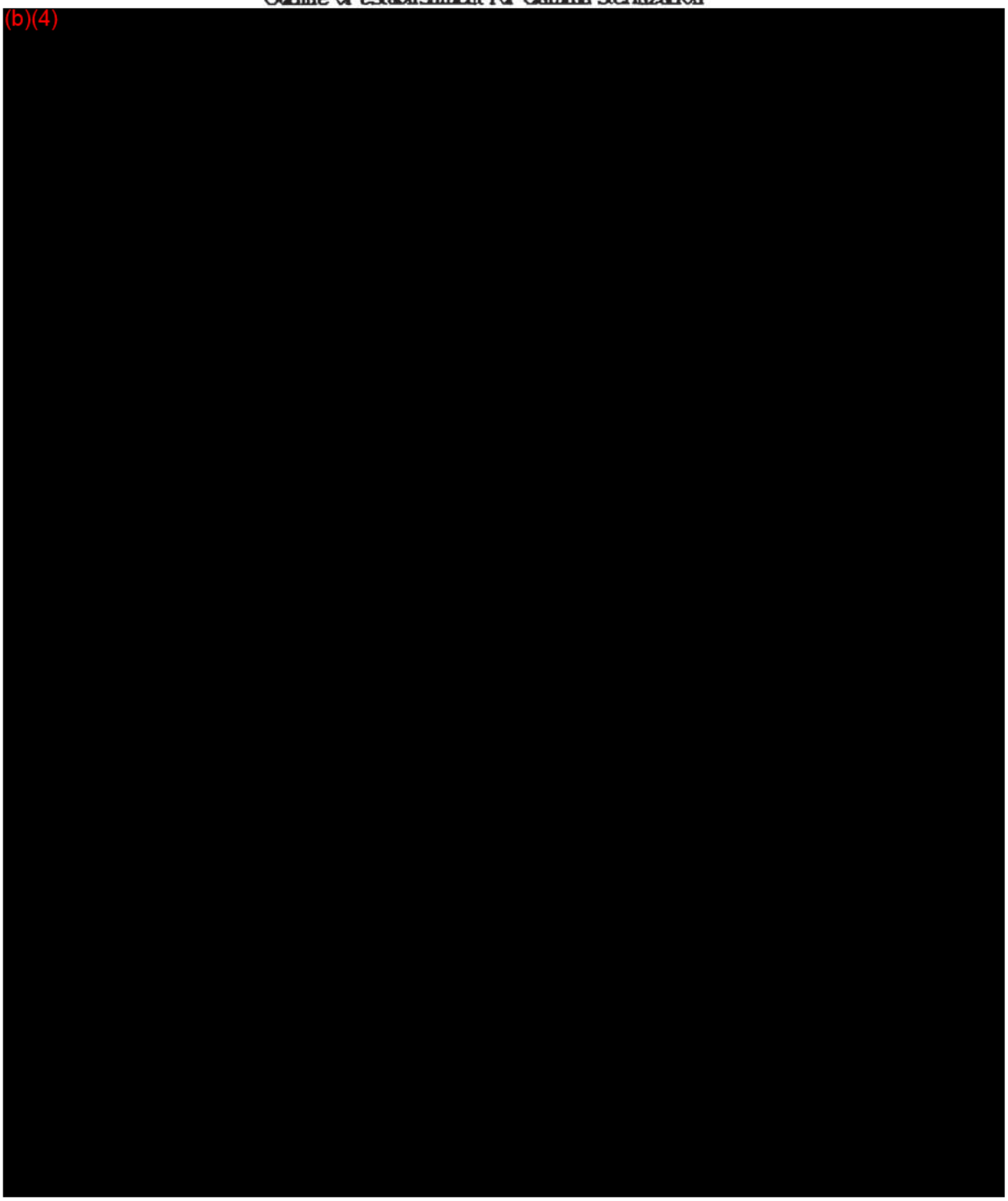
(b)(4)



첨부(Attachment) 19

감마선 멸균 시설의 건축물 현황
Outline of establishment for Gamma sterilization

(b)(4)



첨부(Attachment) 20

팔렛트 감마선 조사기 설치도
Site Map of Pallet Gamma Irradiator

(b)(4)

첨부(Attachment) 21

운송 콘베이어 체계

Conveyer system for Carrier movement

(b)(4)

첨부(Attachment) 22

캐리어 이송경로
Pathway of Carriers

(b)(4)

첨부(Attachment) 23

적재 운송기 설계
Loading Carrier Design

(b)(4)

첨부(Attachment) 24

조사시설의 운영
Operation of irradiation plant
(Irradiator operating Panel)

(b)(4)

첨부(Attachment) 25

사이클 타이머 교정성적서
Certificate of Calibration

Calibration item :
EAGLE SIGNAL TIMER

(Setting time for irradiation)

(b)(4)

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선량 측정 시스템 교정 성적서
Certificate of Dosimetry system

Calibration item :

1. Spectrophotometer

Calibration institute :

(b)(4) [redacted]

2. Thickness gauge

Calibration institute :

(b)(4) [redacted]

(b)(4) [redacted]

3. Routine Dosimeters

Calibration institute :

(b)(4) [redacted]

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첨부(Attachment) 27

설비의 선량분포도
Installation Dose Mapping

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Test Results Report

Issue No. : (b)(4)

(b)(4)

Company Name : NIBEC Co. Ltd.

Representative person : (b)(4)

Product Name : Dental bone graft material (OCS-B)

The results on samples received from the applicant to submit reports.

(b)(4)

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Final Report

Dental bone graft material(OCS-B) Intraosseous transplantation of the rabbit test in the 12 weeks

(b)(4) [redacted]

July 19, 2005

(b)(4) [redacted]

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Final Report

Dental bone graft material (OCS-B) of the sterility test (b)(4) [redacted]

July 19, 2005

(b)(4) [redacted]

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Final Report

Dental bone graft material (OCS-B) the weight of the test

(b)(4) [redacted]

July 19, 2005

(b)(4) [redacted]

(b)(4)

(b)(4)

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(b)(4)

Final Report

Dental bone graft material (OCS-B) tests of moisture content

(b)(4) [redacted]

July 19, 2005

(b)(4) [redacted]

(b)(4)

(b)(4)

(b)(4)

(b)(4)

Final Report

Dental bone graft material (OCS-B) of the particle size test

(b)(4)

[redacted]

July 19, 2005

(b)(4)

[redacted]

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K113246/S2 V. 1

DEPARTMENT OF HEALTH & 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

August 02, 2012

NIBEC COMPANY, LIMITED
C/O PATS CORP.
4568 W. 1ST STREET
SUITE 104
LOS ANGELES, CALIFORNIA 90004
ATTN: DANIEL NAM

510k Number: K113246

Product: OCS-B

Extended Until: 08/31/2012

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information (AI) is not received by the "Extended Until" date shown above, your premarket notification will be considered withdrawn (21 CFR 807.87(l)). If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

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

PATS corp.
CERTIFICATION BUSINESS

4568 W. 1st Street, Suite 104
Los Angeles, California, 90004
email: pats0433@yahoo.com
Phone: 213-626-1544 FAX: 213-626-1548

July 25, 2012
Document Mail Center
Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring. MD20993-0002

RE: Request for extension of the revised submission (K113246)

Reference: K113246
Product: OCS-B
Submitter: NIBEC Co., Ltd.
Applicant: PATS CORP
Manufacturer: NIBEC Co., Ltd.

Dear Lauren Giles,

We appreciate your comments on our 510K submission. We have received your letter of requirements regarding the product with the 510K number, **K113246** as shown above.
All of your comments are being considered and reflected in our revised submission.
To this regard, we would like to extend the submission deadline as Aug 31st, 2012.
If you have any question, please feel free to contact me. Thanks.

Best regards,

Daniel

Daniel Nam (General Manager)
Authorized Agent of 510K Applicant

1 of 2

Payne, Melissa T*

From: Microsoft Outlook
To: 'pats0433@yahoo.com'
Sent: Tuesday, July 03, 2012 2:45 PM
Subject: Relayed: K113246 FDA Extension Letter

Delivery to these recipients or distribution lists is complete, but delivery notification was not sent by the destination:

'pats0433@yahoo.com'

Subject: K113246 FDA Extension Letter

Sent by Microsoft Exchange Server 2007

DEPARTMENT OF HEALTH & 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

July 03, 2012

NIBEC COMPANY, LIMITED
C/O PATS CORP.
4568 W. 1ST STREET
SUITE 104
LOS ANGELES, CALIFORNIA 90004
ATTN: DANIEL NAM

510k Number: K113246

Product: OCS-B

Extended Until: 08/10/2012

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information (AI) is not received by the "Extended Until" date shown above, your premarket notification will be considered withdrawn (21 CFR 807.87(l)). If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

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

PATS corp.
CERTIFICATION BUSINESS

4568 W. 1st Street, Suite 104
Los Angeles, California, 90004
email: pats0433@yahoo.com
Phone: 213-626-1544 FAX: 213-626-1548

June 27, 2012
Document Mail Center
Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring. MD20993-0002

RE: Request for extension of the revised submission (K113246)

Reference: K113246
Product: OCS-B
Submitter: NIBEC Co., Ltd.
Applicant: PATS CORP
Manufacturer: NIBEC Co., Ltd.

Dear Lauren Giles,

We appreciate your comments on our 510K submission. We have received your letter of requirements regarding the product with the 510K number, **K113246** as shown above.
All of your comments are being considered and reflected in our revised submission.
To this regard, we would like to extend the submission deadline as Aug 10th, 2012.
If you have any question, please feel free to contact me. Thanks.

Best regards,

Daniel

Daniel Nam (General Manager)
Authorized Agent of 510K Applicant

* * * COMMUNICATION RESULT REPORT (JUN. 18. 2012 2:29PM) * * *

FAX HEADER 1:
FAX HEADER 2:

TRANSMITTED/STORED : JUN. 18. 2012 2:27PM				
FILE MODE	OPTION	ADDRESS	RESULT	PAGE
6664 MEMORY TX		912136261548	OK	2/2

REASON FOR ERROR
E-1) HANG UP OR LINE FAIL
E-2) BUSY
E-3) NO ANSWER
E-4) NO FACSIMILE CONNECTION

DEPARTMENT OF HEALTH & 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

June 18, 2012

NIBEC COMPANY, LIMITED
C/O PATS CORP.
4568 W. 1ST STREET
SUITE 104
LOS ANGELES, CALIFORNIA 90004
ATTN: DANIEL NAM

510k Number: K113246
Product: OCS-B
On Hold As of 6/15/2012

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

DEPARTMENT OF HEALTH & 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

June 18, 2012

NIBEC COMPANY, LIMITED
C/O PATS CORP.
4568 W. 1ST STREET
SUITE 104
LOS ANGELES, CALIFORNIA 90004
ATTN: DANIEL NAM

510k Number: K113246
Product: OCS-B
On Hold As of 6/15/2012

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Lauren Gyles

Subject: 510(k) Number K113246/S2

To: The Record

Please list CTS decision code TH

- ☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)
- ☐ Hold (Additional Information or Telephone Hold).
- ☐ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

☐	NO	NSE for lack of predicate
☐	NI	NSE for new intended use
☐	NQ	NSE for new technology that raises new questions of safety and effectiveness
☐	NU	NSE for new intended use AND new technology raising new questions of safety and effectiveness
☐	NP	NSE for lack of performance data
☐	NS	NSE no response
☐	NL	NSE for lack of performance data AND no response
☐	NM	NSE pre-amendment device call for PMAs (515i)
☐	NC	NSE post-amendment device requires PMAs
☐	NH	NSE for new molecular entity requires PMA
☐	TR	NSE for transitional device

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*		
510(k) Summary /510(k) Statement	*Attach Summary*		
Truthful and Accurate Statement.	*Must be present for a Final Decision*		
Is the device Class III?			
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			
Is clinical data necessary to support the review of this 510(k)?			
For United States-based clinical studies **only**: Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If study was			

conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)

Does this device include an Animal Tissue Source?

All Pediatric Patients age<=21

Neonate/Newborn (Birth to 28 days)

Infant (29 days -< 2 years old)

Child (2 years -< 12 years old)

Adolescent (12 years -< 18 years old)

Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)

Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)

Nanotechnology

Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html) *Contact OC.*

Regulation Number	**Class***	**Product Code**

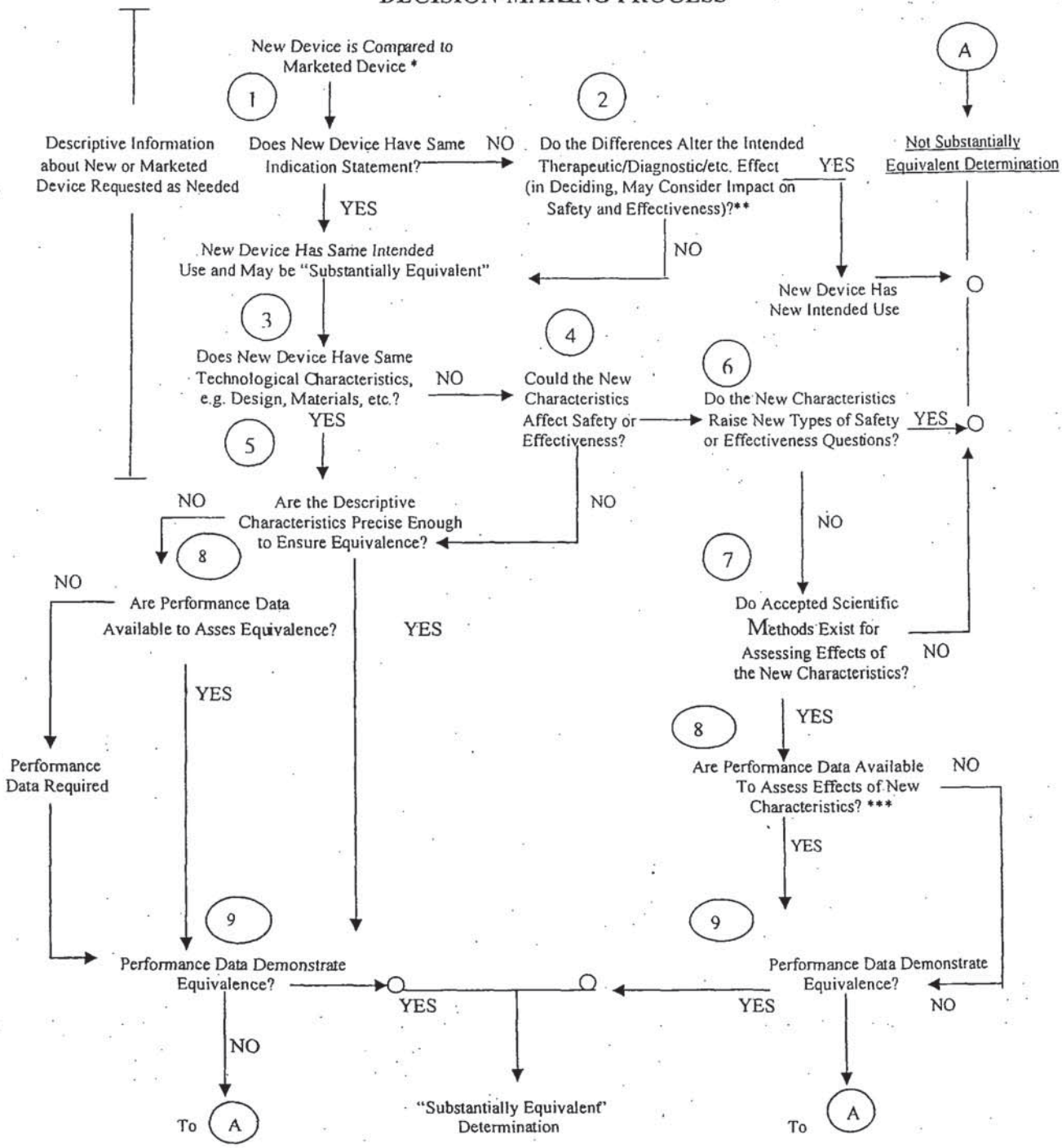
(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: _____ (Branch Chief) _____ (Branch Code) 6/15/12 (Date)

Final Review: _____ (Division Director) 6/15/12 (Date)

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

DEPARTMENT OF HEALTH AND HUMAN SERVICES MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Premarket Notification [510(k)] Review
Traditional/Abbreviated

Telephone Hold #2

K113246/S002

Date: June 15, 2012

To: The Record Office: ODE

From: Lauren Giles, Biomedical Engineering Division: DAGID

510(k) Holder: NIBEC Co., Ltd., of Chungcheongbuk-do, Korea

Device Name: *OCS-B* (K113246/S002)

Contact: Mr. Daniel Nam

Phone: 1-213-626-1544

Fax: 1-213-626-1548

Email: Pats0433@yahoo.com

I. Purpose and Submission Summary

NIBEC Co., Ltd., of Chungcheongbuk-do, Korea, has submitted a Premarket Notification (510(k)) to introduce into U.S. interstate commerce *OCS-B*, an organic bovine bone filling material. *OCS-B* is a prescription Class II medical device regulated under 21 CFR 872.3930 as a "Bone Grafting Material." The *OCS-B* is listed under product code NPM.

The submission for *OCS-B* consists of Form FDA 3674, Form FDA 3514, 510(k) Cover Letter, Truthful and Accurate Statement, Indication for Use, Safety and Effectiveness Statement, Screen Checklist, FDA Form 3674, Form 3654, Label and Package, User Manual, Product Description, Sterility Validation Report, Substantial Equivalence Report, Biocompatibility and Performance Test report, Risk Analysis Report, Clinical data, 510(k) Summary, Viral Inactivation report.

The primary mode of action for this device is grafting to dental defect to promote bone growth. The submission claims substantial equivalence to *BIO-OSS, BIO-OSS BLOCKS and BIO-OSS Collagen* (K033815).

The submission references the following standards in Form FDA 3514 but has provided Form FDA 3654 for all standards referenced.

Standard	Standard Title	Version
IEC 980	Graphical symbols for use in labeling of medical devices	2003
IEC 1041	Information supplied by the manufacturer with medical devices	1998
ISO 10993-1	Biological evaluation of medical devices – Part 1: Evaluation and Testing	2003
ISO 10993-5	Biological evaluation of medical devices – Part 5: Test for In Vitro Cytotoxicity	
ISO 10993-10	Biological evaluation of medical devices – Part 10: Test for irritation and delayed-type hypersensitivity	2002
ISO 10093-11	Biological evaluation of medical devices – Part 11: Test for system toxicity	2002
ISO 10093-6	Biological evaluation of medical devices – Part 6: Test for local effects after implantation	2007
ISO 14971	Medical Devices – Application of risk management to medical devices	2007

Reviewer's Notes:

- *In Form FDA 3514 the applicant lists the device classification as unknown; in addition on page 52 of the submission the applicant lists the device classification as Class III. However, under the NPM product code, the proposed device is consider Class II and contains special controls and FDA issued guidance document for "Dental Bone Grafting Material" and "Medical Devices Containing Materials Derived for Animal Sources."*
- *Form FDA 3654 has not provided for all the standards listed in Form FDA 3514. In addition, the submission references to several other standards on page 52 of the submission and in the sterilization and performance testing reports. Form FDA 3654 should be provided for all standard referenced or relied on in this submission.*

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription)			
(Indicate if: OTC)			
Truthful and Accuracy Statement			
Standards Form			

	YES	NO	N/A
Required Elements for 510(k) Summary (21 CFR 807.92)			
Clearly labeled "510(k) Summary"	X		
Submitter' s name, address, phone #, a contact person		X	
Date the summary was prepared		X	

			YES	NO	N/A
	The name of the device/trade name/common name/classification name			X	
	An identification of the legally marketed Predicate		X		
	Description of the subject device			X	
	Statement of intended use(identical to indications for use)		X		
	Technological	if same, a summary of comparison of technological characters		X	
		If different, a summary of how do they compare to the Predicate		X	
	Performance Data	Brief discussion of non-clinical data submitted, referenced, or relied on		X	
		Brief discussion of clinical data submitted, referenced, or relied on, including: ▪ Description upon whom the device was tested, ▪ Data obtained from the tests and especially: ▪ Adverse events and complications ▪ Other information for SE determination		X	
		Conclusion that data demonstrate SE		X	
Required Elements for <u>510(k) Statement</u> (21 CFR 807.93)					
	Signed verbatim statement		X		

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?	X		
Does the device design use software?		X	
Is the device sterile?	X		
Is the device reusable (not reprocessed single use) and are "cleaning" instructions included for the end user?		X	

OSC-B is an anorganic xenogeneic bone grafting material. *OSC-B* is composed of bovine natural hydroxyapatite derived for Korean native cattle bone. OCS-B is provided in three

types: a vial, bowl, or syringe. All three types are supplied as cancellous granules or cortical granules. The particle size of *OSC-B* ranges from 0.212mm to 2.0mm. The Ca/P ratio of *OCS-B* is 1.66.

The device description includes a step-by-step flow chart and narrative of the manufacturing process for *OSC-B*. The raw material is soaked twice in purified water for 6-15 hours. The material is then heated for no more than 6 hours a day and washed of the fatty/flesh substance and dried for 12 hours at 120°C. The dried bovine bone is then classified as either cancellous or cortical and crushed. The crushed particles are soaked on methanol, chloroform, and sodium hypochlorite followed by washing in purified water. The material is then tested for the presence of proteins using a protein assay. If no proteins are detected the material passes. The material is then tested using a pH assay; if the material passes it is placed in a sieve for crushing to the desired particle size.

The risk analysis also provides addition details of *OSC-B*. *OSC-B* is produced only using the apatite component from the bovine thigh bone and is intended for direct implantation into the bony defect. It is intended to have a 3-6 month healing period where 30-50% of the granules are absorbed into the tissue.

Reviewer's Notes:

- *Korea is not listed on the FDA guidance document for "Medical Devices Containing Material Derived from Animal Source" as a country which BSE exist or presents a significant risk.*
- *The submission does not include any details on the chemical composition by weight or molar weight for the proposed device. In addition no details can be found on the raising, feeding, vaccination of the cattle.*
- *The submission does not specify the protein assay and what proteins are being tested.*

IV. Indications for Use

OCS-B® is recommended for:

- Augmentation or reconstructive treatment of the alveolar ridge.
- Filling of infrabony periodontal defects.
- Filling of defects after root resection, apicoectomy, and cystectomy.
- Filling of extraction sockets to enhance preservation of the alveolar ridge.
- Elevation of the maxillary sinus floor.
- Filling of periodontal defects in conjunction with products intend for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR).
- Filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration (GBR).

Reviewer's Notes:

The IFUS provided in the submission is not marked for prescription use. The IFUS is identical in wording and content to the declared predicate device.

V. Labeling

The submission includes draft labeling for the packaging and also contains draft Instructions

for Use.

The *OCS-B* products contain several packaging labels including a Tyvek label, paper box, and outer carton box. The labeling include a product description (trade name, particle size, granule type, and weight), the manufacturer information, sterile, single use only, caution to read instructions, lot and expiration date, and the prescription statement as required by 21 CFR 801.109. The labeling contains no symbols and all text is written in the English language.

The submission also includes draft Instructions for Use. The main insert state that *OCS-B* should only be placed in well vascularized bone. *OCS-B* can be mixed with autogenous bone, osseous coagulum, patient's blood or sterile normal saline. For larger defects it should be mixed with autogenous bone in a 1:1 ratio. *OCS-B* should be placed with light/moderate pressure and the defects should not be overfilled. The instructions state the graft site should be allowed to heal for 6 months prior to implant placement.

In addition to the main insert, each type (vial, bowl, and syringe) of *OCS-B* contains directions. These direction include sections for Components and Characteristics, Uses, Instructions, Contraindications, Adverse Reactions, How Supplied, and Storage. The Instructions are similar to that in the main insert. The proposed device is contraindicated for use in people with metabolic diseases, liver disease, and vascular impairment among others. The "How Supplied" section details the all the variations of the granule, weight, and size of *OCS-B* provided for each type (vial, bowl, and syringe). *OCS-B* is to be stored at room temperature.

Reviewer's Notes:

- *The "Components and Characteristics" sections of the directions contain the following unsubstantiated claims:*
  - *"OCS-B is free of organic impurities including inflammatory proteins, lipid, and provides similar nanocrystal structure to human bone."*
  - *"OCS-B facilitates osteoconduction due to its 3-dimensional porous structure and helps mineralization process."*
- *The Uses section should be revised to state "Intended Use." The Intended Use should be identical to the Indications for Use Statement provided in the submission.*
- *The "Instructions" sections of the directions contain the following unsubstantiated claims:*
  - *"Mixing OCS-B cancellous granules and OCS-B cortical granules in a ratio of 1:1 in bone regeneration procedure may result in elevating the strength of new bone."*

VI. Sterilization/Shelf Life/Reuse

(b)(4) [redacted]

(b)(4)

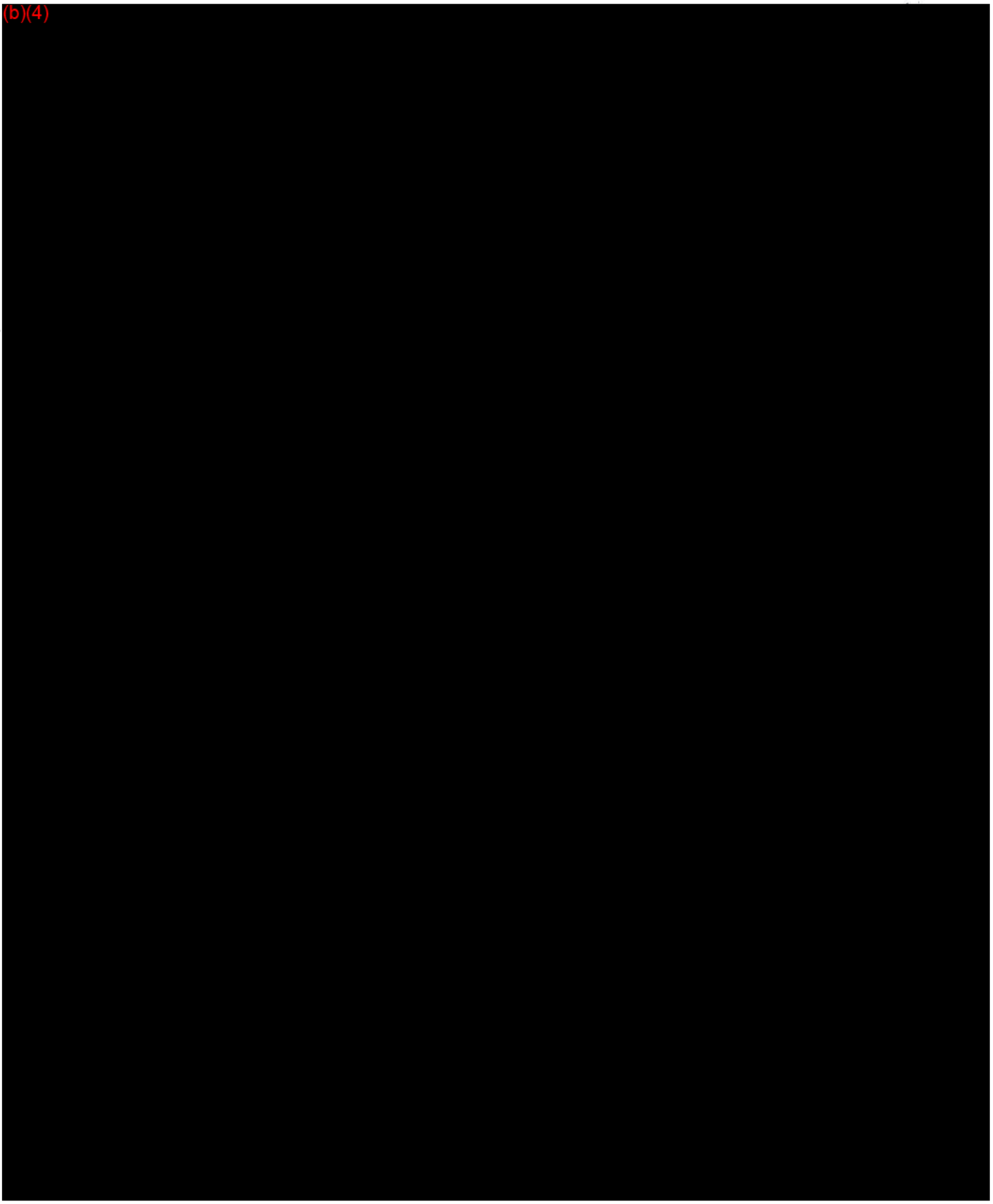
[redacted]

VII. Biocompatibility

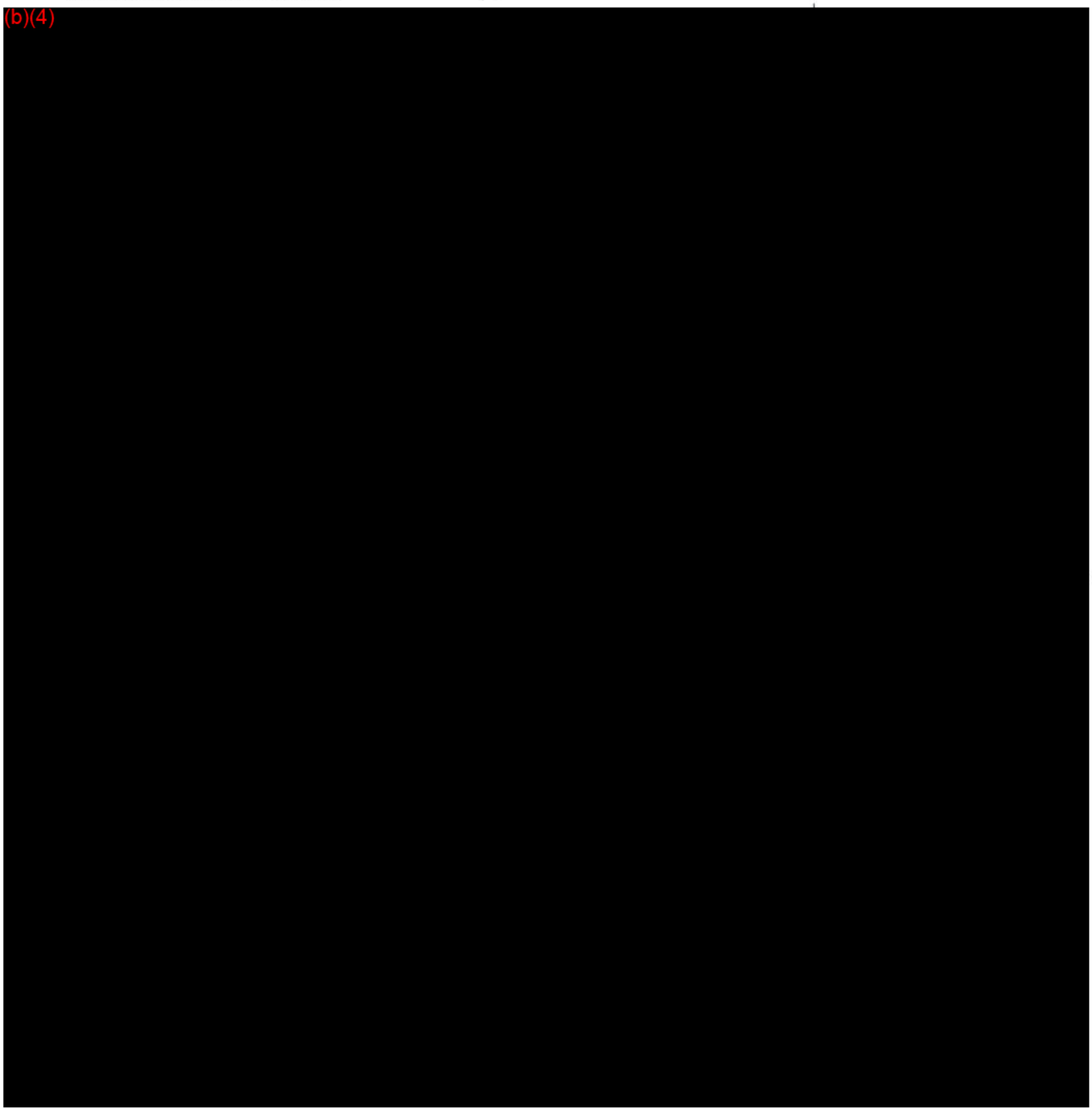
(b)(4)

[redacted]

(b)(4)



(b)(4)



VIII. Software

OSC-B does not appear to contain any software as defined in the scope of FDA's "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". Therefore, software documentation and validation is not required for *OSC-B*.

OCS-B, K113246, NIBEC Co., Ltd.

IX. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

OSC-B does not appear to produce an EM field, utilize electricity, or produce a thermal effect. Therefore, EMC, electrical safety, and thermal safety are not applicable.

X. Performance Testing – Bench

(b)(4)

[redacted]

(b)(4)

(b)(4)

(b)(4)

(b)(4)

[redacted]

Reviewer's Notes:

- *The determination of low crystallinity was determined by SEM image analysis in comparison to a reference device and the declared predicate. The submission states the particles are spherical in shape. Resportion rate increases as the crystallinity of HA decreases. Crystallinity is highly dependence on the sintering temperature. The higher the sintering temperature the more crystalline the HA.*

XI. Performance Testing – Animal

Section 7 of the submission includes a clinical evaluation of the proposed device. Included in the clinical evaluation in section 7.2.3 and Annex 7-3 is an Animal Study for *OCS-B*. (b)(4)

(b)(4)

[redacted]

(b)(4)

[redacted]

XII. Performance Testing – Clinical

(b)(4)

[redacted]

XIII. Predicate Device Comparison

The submission claims substantial equivalence to *BIO-OSS, BIO-OSS BLOCKS and BIO-OSS Collagen* (K033815). However, this is a special for change in the cattle source to Australian cows. The original *BIO-OSS*, an anorganic bovine bone, was cleared in K871773.

XIV. Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?			If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
3. Same Technological Characteristics?			If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?			If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
8. Performance Data Available?			If **NO** = Request Data
9. Data Demonstrate Equivalence?			Final Decision:

Note: See http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

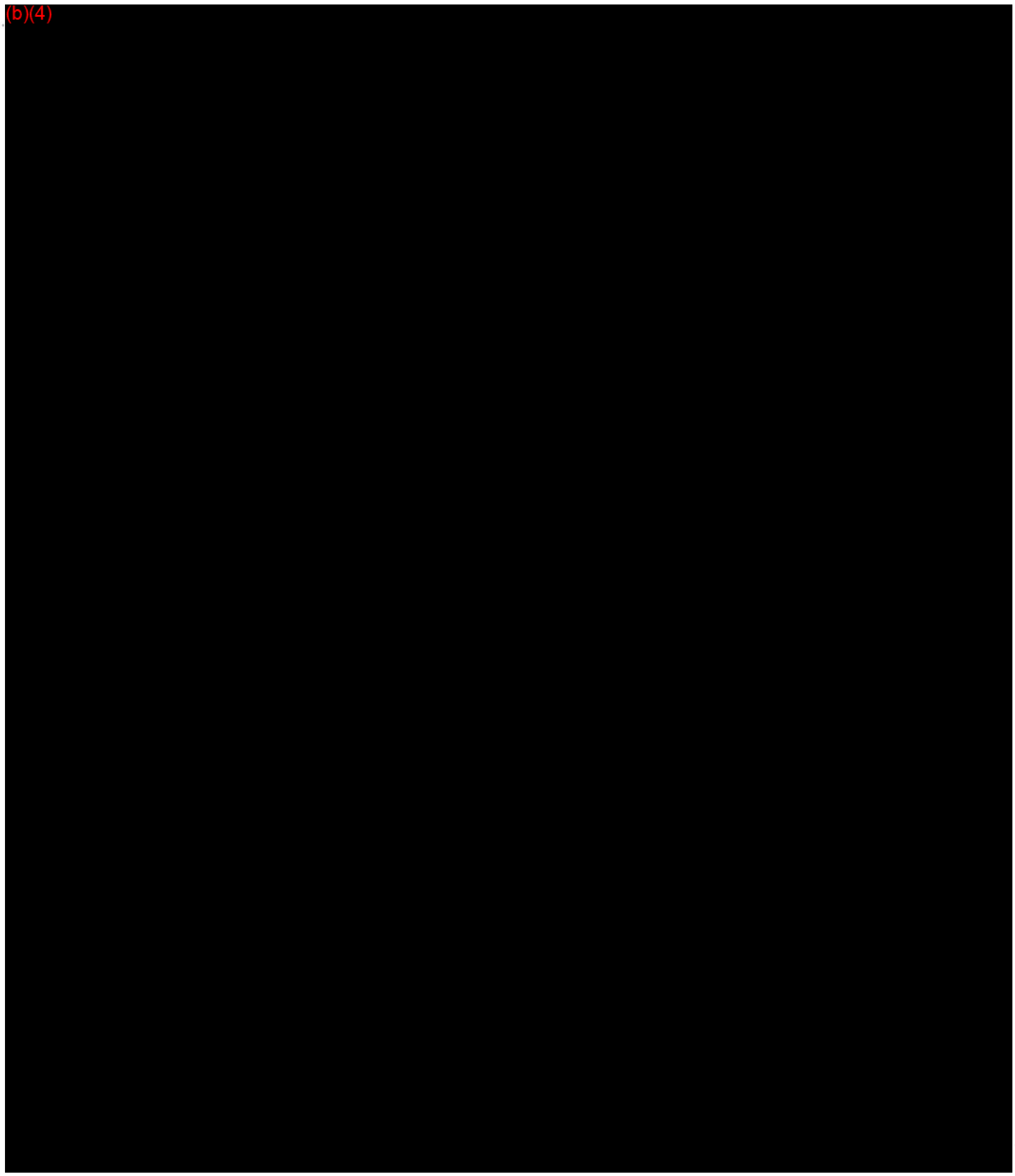
1. Explain how the new indication differs from the predicate device's indication:
2. Explain why there is or is not a new effect or safety or effectiveness issue:
3. Describe the new technological characteristics:
4. Explain how new characteristics could or could not affect safety or effectiveness:
5. Explain how descriptive characteristics are not precise enough:
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
7. Explain why existing scientific methods can not be used:
8. Explain what performance data is needed:
9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

XV. Deficiencies

(b)(4)

[redacted]

(b)(4)



(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

[redacted]

XVI. Contact History

11/2/11 – Original Submission Recieved

12/1/11 – TH1: On December 1, 2011 applicant was contacted via email and provided with the deficiency listed on the same date and advise the submission will be place on telephone hold.

3/23/12 – TH2: On March 23, 2012 applicant was contacted via email and provided with the deficiency listed for the same date and advise the submission will be place on telephone hold.

6/15/12 – TH2: On June, 2012 applicant was contacted via email and provided with the deficiency listed for the same date and advise the submission will be place on telephone hold.

XVII. Recommendation

Telephone Hold.

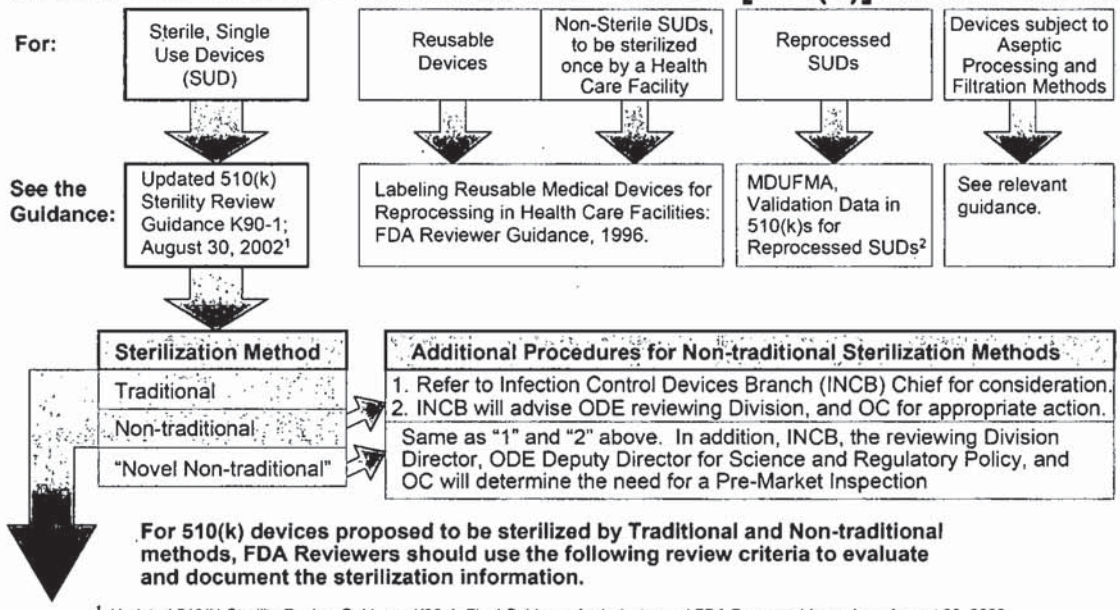
Reviewer
Lauren Giles, B.S. BME
Biomedical Engineer

6/15/12
Date

Branch Review
M. Susan Runner, D.D.S., M.A.
Branch Chief Dental Devices

Date

Sterile Devices in Premarket Notification [510(k)] Submissions



For 510(k) devices proposed to be sterilized by Traditional and Non-traditional methods, FDA Reviewers should use the following review criteria to evaluate and document the sterilization information.

[1] *Updated 510(k) Sterility Review Guidance K90-1; Final Guidance for Industry and FDA Document Issued on: August 30, 2002*
[2] *Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single Use Devices*

1. Sterilant:	YES	NO
a. **Sterilization method** description (e.g., Steam, EtO, Radiation):	Gamma Radiation	
b. **Dose**, for radiation (e.g., 25 – 40 kGy):	25kGy	
c. **Sterilant residuals** remaining on the device: For EO, the maximum levels of residuals of EO and ethylene chlorhydrin that remain on the device (note: not to include ethylene glycol residual level because the recognized standard, "ANSI/AAMI/ISO 10993-7:1995 Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide sterilization residuals," does not include measurement of ethylene glycol residuals);	N/A	
2. A description of the Validation Method for the sterilization cycle (not data): (Citation of an FDA recognized standard is acceptable (e.g., ANSI/AAMI/ISO 11135))	ISO 11137-1,-2 VDMax	
3. Sterility assurance level (SAL): (e.g., 10^{-6} for all devices (except 10^{-3} for devices that contact intact skin))	10^{-6}	
4. Is it labeled "Pyrogen Free"?	??	
If so, a description of the method: (e.g., LAL (*Limulus* Amebocyte Lysate test))		
5. A description of the packaging (not including package integrity test data):	See memo Sec. VI	

Giles, Lauren

From: Giles, Lauren
Sent: Friday, June 15, 2012 3:00 PM
To: 'Gilltaik Gong'
Subject: OCS-B (K113246) Additional Information Request and Telephone Hold

Mr. Nam,

I have been assigned to the review of *OCS-B (K113246)*. After continued review of your submission, I have come across the following deficiency in the submission that should be addressed to facilitate a complete review of your submission:

(b)(4)

(b)(4)

I am placing this document on telephone hold pending the submission of information in response to these requests and the determination that this information fulfills each request. In order to remove this document from its hold status, you must submit this information in hard copy to the Document Mail Center at the same address to which your original submission was sent. In addition, please send an electronic copy of your response to me via email. I am available to review any information you are considering before its official submission in order to ensure that it fulfills these requests.

Please contact me with questions or concerns.

Sincerely,

Lauren Giles
iomedical Engineer/Reviewer
FDA/ODE/DAGID/DEDB
10903 New Hampshire Avenue
WO66 - Rm. 2546
Silver Spring, MD 20993
phone: 301-796-9552
fax: 301-847-8109
Lauren.Giles@fda.hhs.gov

DEPARTMENT OF HEALTH & 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

June 13, 2012

NIBEC COMPANY, LIMITED
C/O PATS CORP.
4568 W. 1ST STREET
SUITE 104
LOS ANGELES, CALIFORNIA 90004
ATTN: DANIEL NAM

510k Number: K113246

Product: OCS-B

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

Grayson, Giovanna *

From: Grayson, Giovanna *
Sent: Wednesday, June 13, 2012 2:07 PM
To: 'pats0433@yahoo.com'
Subject: ACK LETTER
Attachments: image002.png

DEPARTMENT OF HEALTH & 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

June 13, 2012
NAM
DANIEL
NIBEC COMPANY, LIMITED
C/O PATS CORP.
4568 W. 1ST STREET
SUITE 104
LOS ANGELES, CALIFORNIA 90004
ATTN: DANIEL NAM

510k Number: K113246

Product: OCS-B

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510 (k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

K113246/S2

June 4, 2012

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

510K Number: K113246
Response to Information Request
Product: OCS-B (b)(4)

To Whom It May Concern:

NIBEC herewith submits in duplicate our response to the deficiencies outlined in Ms. Lauren Giles' email dated March 24, 2012 **(see Tabular – Initial FDA Comments - email dated 3/24/2012)** to 510(k) Number K113246, OCS-B (bovine derived hydroxyapatite).

On May 15, 2012 the FDA granted additional time to respond to the information request until June 11, 2012.

We are confident that the responses provided address the concerns raised in Ms Giles' email support Agency clearance of the above-referenced 510(k) notification for OCS-B. We would like to thank the Division for its review of our submission.

****

For ease of review of this submission, data displays and discussion have been incorporated into the responses wherever possible. Where additional data or information is required, it is included as an Attachment.

For the convenience of the reviewer, we repeat below in **BOLD** the deficiencies conveyed by Ms. Lauren Giles, followed by NIBEC's response to each deficiency.

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Risk management Report

Product name : OCS-B™

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INDICATIONS FOR USE

510(K) Number : K113246
Device Name : OCS-B™

INDICATIONS for USE :
OCS-B™ cancellous and cortical granules are recommended for :

1. Augmentation or reconstructive treatment of the alveolar ridge.
2. Filling of infrabony periodontal defects.
3. Filling of defects after root resection, apicoectomy, and cystectomy.
4. Filling of extraction sockets to enhance preservation of the alveolar ridge.
5. Elevation of the maxillary sinus floor.
6. Filling of periodontal defects in conjunction with products intend for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR)
7. Filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration (GBR).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Attachment 11 : Declaration of conformity and FDA form 3654

10.0 Declaration of conformity and FDA form 3654

Declaration of conformity

OCS-B™ is manufactured in accordance with the U.S. Food and Drug Administration's Quality System Regulation (21 C.F.R. Part 820) and the ISO International Medical Device Quality Management System Standard 13485. In developing OCS-B™, the Sponsor and the product's manufacturer followed:

- FDA's "Class II Special Controls Guidance Document : Dental Bone Grafting Material Devices "(Issued April 28, 2005)

Specifically, the product was evaluated and tested in accordance with :

- ISO 10993 "Biological Evaluation of Medical Devices"
- ASTM F 1581-99 "Standard Specification for Composition of Anorganic Bone for Surgical Implants"(1999)
- FDA 's "Medical Device Material Derived from Animal Sources"(1998)
- ISO 11137 "Sterilization of Healthcare Products-Radiation"
- ASTM F1980-99 "Standard Guide for Accelerated Aging of Sterile Medical device Packages"

Testing against the ISO 10993 and ASTM F1581-99 standards was performed by the following state certified contract laboratory:

Seoul National University Hospital
Clinical Trials center
Seoul National University Hospital
Seoul 110-744, Korea

Korea Testing and Research Institute for Chemical Industry
88-2, 8th YeongDeungPo-Dong, YeongDeungPo-Gu,
Seoul 150-038, Korea

Testing against the ISO 11137 standard was performed by the following FDA-registered contract sterilizer:

Greenpia Technology, Inc.
329 Shinji-Ri, Neungseo-Myun
Yujoo-Kun
Kungki-Do, Korea

Testing against the ASTM F1980-99 standard was performed by:

NIBEC CO., LTD.
Iwol electricity-electronic Agro-Industrial Complex
1127, Sinwol-ri, Iwol-myeon, Jincheon-gun
Chungcheongbuk-do, 365-824, Korea

A Form FDA 3654 for each standard cited above(and relevant parts thereto)is included in the following pages. Test results, where applicable, are reported in this submission.

Signature : _____

Dr. Park, Yoon-Jeong
Quality manager of NIBEC

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 9010-0120
Expiration Date: August 31, 2010.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
	(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)*		
NIBEC CO., LTD.			
Division Name *(if applicable)*	Phone Number *(including area code)*		
	(82) 43-532-7458		
Street Address	FAX Number *(including area code)*		
Iwol electricity-electronic Agro-industrial Complex, 1127, Sinwol-ri	( )		
City	State / Province	ZIP/Postal Code	Country
Jincheon-gun,	Chungcheongbuk-do,	451-864	KOREA
Contact Name			
Chong Pyoung Chung			
Contact Title	Contact E-mail Address		
President	pats0433@yahoo.com		

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

Company / Institution Name			
PATS CORP			
Division Name *(if applicable)*	Phone Number *(including area code)*		
	(213) 626-1544		
Street Address	FAX Number *(including area code)*		
1415-1441 Gardena Ave	(213) 626-1548		
City	State / Province	ZIP/Postal Code	Country
Glendale	CA	91204	USA
Contact Name			
Daniel Nam			
Contact Title	Contact E-mail Address		
Representative	Pats0433@yahoo.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
- ☐ Process change:
  - ☐ Manufacturing
  - ☐ Sterilization
  - ☐ Packaging
  - ☐ Other *(specify below)*
- ☐ Response to FDA correspondence:
- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*
- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*
- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment
- ☐ 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

1	NPM	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- [x] 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	k033815	BIO-OSS®, BIO-OSS® Blocks,	Geistlich Pharma Ag
2			
3			
4			
5			
6			

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

bone grafting material, animal source

	Trade or Proprietary or Model Name for This Device	Model Number
1	OCS-B	
2		
3		
4		
5		

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

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

- [ ] Laboratory Testing
- [x] Animal Trials
- [x] Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
NPM	872.3930	[ ] Class I [ ] Class II [ ] Class III [x] Unclassified

Classification Panel

bone grafting material, animal source

Indications *(from labeling)*

Intended for use in dental surgery. The
products may be used in surgical procedures such as:* Augmentation or reconstructive treatment of alveolar ridge
* Filling of periodontal defects
* Filling of defects after root resection, apicocectomy, and cystectomy
* Filling of extraction sockets to enhance preservation of the alveolar ridge
* Elevation of maxillary sinus floor

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	Facility Establishment Identifer (FEI) Number	☑ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler
Company / Institution Name: NIBEC CO., LTD.		Establishment Registration Number
Division Name *(if applicable)*		Phone Number *(including area code)*: (82) 43-532-7458
Street Address: Iwol electricity-electronic Agro-industrial Complex, 1127, Sinwol-ri, Iwol-m		FAX Number *(including area code)*: ( )
City: Jincheon-gun,	State / Province: Chungcheongbuk-do,	ZIP/Postal Code: 451-864 — Country: KOREA
Contact Name: Chong Pyoung Chung	Contact Title: President	Contact E-mail Address: pats0433@yahoo.com

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifer (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ 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

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifer (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ 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	10993-1	ISO	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk manangement process	2009	
2	10993-3	ISO	Biological evaluation of medical devices Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	2003	
3	10993-5	ISO	Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity	2009	
4	10993-6	ISO	Biological evaluation of medical devices -- Part 6: Tests for local effects after implantation	2007(R)/2010	
5	10993-10	ISO	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	2010	
6	10993-11	ISO	Biological evaluation of medical devices Part 11: Tests for systemic toxicity	2006	
7	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	

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

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	11137-2	ISO	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose	2006	
2	F1980-99	ASTM	Standard Guide for Accelerated Aging of Sterile Medical Device Packages		
3	F1581-99	ASTM	Standard Specification for Composition of Anorganic Bone for Surgical Implants		
4					
5					
6					
7					

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

See OMB Statement on Reverse. Form Approved: OMB No. 0910-0616, Expiration Date: 06-30-2008

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER
NIBEC Co., Ltd.

2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
09/02/2011

3. ADDRESS *(Number, Street, State, and ZIP Code)*
Iwol electricity-electronic Agro-industrial Complex, 1127, Sinwol-ri, Iwol-myeon, Jincheon-gun, Chungcheongbuk-do, Korea

4. TELEPHONE AND FAX NUMBER *(Include Area Code)*
(Tel.) 82 43-532-7458
(Fax) 82 43-537-1714

PRODUCT INFORMATION

5. **FOR DRUGS/BIOLOGICS:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
(Attach extra pages as necessary)

Device Classification Name : Bone Grafting Material, Animal Source
Dental Bone Grafting Material

Device Name: Natural Bone Mineral Matrix, Anorganic Bovine Bone Grafting Material

Product Code : NPM

Trade name: OCS-B

21 CFR 872.3930

Device Class : Class II

APPLICATION / SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER *(If number previously assigned)*

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

CERTIFICATION STATEMENT / INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES *(See instructions for additional information and explanation)*

☐ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

☐ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

☒ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/ SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES *(Attach extra pages as necessary)*

NCT Number(s):

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.
Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign)

12. NAME AND TITLE OF THE PERON WHO SIGNED IN NO. 11
(Name) Daniel Nam
(Title) General Manager

13. ADDRESS *(Number, Street, State, and ZIP Code) (of person identified in No. 11 and 12)*
1415-1441 Gardena Ave.,Glendale, CA 91204

14. TELEPHONE AND FAX NUMBER *(Include Area Code)*
(Tel.) 213-626-1544
(Fax) 213-626-1548

15. DATE OF CERTIFICATION
09/02/2011

FDA-3674 (1/08) (FRONT)

PSC Graphics (301) 443-1090 EF

Instructions for Completion of Form FDA 3674

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))
Form 3674 must accompany an application/submission, including amendments, supplements, and resubmissions, submitted under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.

1. **Name of Sponsor/Applicant/Submitter -** This is the name of the sponsor/applicant/submitter of the drug/biologic/device application/ submission which the certification accompanies. The name must be identical to that listed on the application/submission.

2. **Date -** This is the date of the application/submission which the certification accompanies.

3. **& 4. -** Provide complete address, telephone number and fax number of the sponsor/applicant/submitter.

5. **Product Information - For Drugs/Biologics:** Provide the established, proprietary name, and/or chemical/biochemical/blood product/ cellular/gene therapy name(s) for the product covered by the application/submission. Include all available names by which the product is known. **For Devices:** Provide the common or usual name, classification, trade or proprietary or model name(s), and/or model number(s). Include all available names/model numbers by which the product is known.

6. **Type of Application/Submission -** *Identify the type of application/submission which the certification accompanies by checking* the appropriate box. If the name of the type of application/submission is not identified, check the box labeled "Other."

7. **IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/Other Number -** If FDA has previously assigned a number associated with the application/ submission which this certification accompanies, list that number in this field. For example, if the application/submission accompanied by this certification is an IND protocol amendment and the IND number has already been issued by FDA, that number should be provided in this field.

8. **Serial Number -** In some instances a sequential serial number is assigned to the application. If there is such a serial number, provide it in this field.

9. **Certification -** This section contains three different check-off boxes.
   Box A should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply because no clinical trials are included, relied upon, or otherwise referred to, in the application/ submission which the certification accompanies.

   Box B should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply at the time of submission to any clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, at the time the application/submission is being made, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply to any of the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies.

   Box C should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do apply at the time of submission to some or all of the clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, at the time the application/ submission is being made, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, apply to one or more of the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies.

10. **National Clinical Trial (NCT) Numbers -** If you have checked Box C in number 9 (Certification), provide the NCT Number obtained from www.ClinicalTrials.gov for each clinical trial that is an "applicable clinical trial" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, and that is included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Type only the number, as NCT will be added automatically before number. Include any and all NCT numbers assigned to the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies. Multiple NCT numbers may be required for a particular certification, depending on the number of "applicable clinical trials" included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies.

11. **Signature of Sponsor/Applicant/Submitter or an Authorized Representative -** The person signing the certification must sign in this field.

12. **Name and Title of Person Who Signed in number 11. -** Include the name and title of the person who is signing the certification. If the person signing the certification is not the sponsor/applicant/submitter of the application/submission, he or she must be an authorized representative of the sponsor/applicant/submitter.

13. **& 14. -** Provide the full address, telephone and fax number of the person who is identified in number 11 and signs the certification in number 11.

15. Provide the date the certification is signed. This date may be different from the date provided in number 2.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 15 minutes and 45 minutes (depending on the type of application/submission) per response, including time for reviewing instructions. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to the applicable address below.

Food and Drug Administration
Center for Drug Evaluation and Research
Central Document Room
Form No. FDA 3674
5901-B Ammendale Road
Beltsville, MD 20705-1266

Food and Drug Administration
Center for Biologics Evaluation and Research
1401 Rockville Pike
Rockville, MD 20852-1448

Food and Drug Administration
Center for Devices and Radiological Health
Program Operations Staff (HFZ-403)
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 number.

FDA-3674 (1/08) (BACK)

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)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO-10993-1 : Biological Evaluation of Medical Devices - Part 1 : Evaliuation 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 tests? 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: Class II Special Controls Guidance Document : Dental Bone Grafting Material Devices

[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 and 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 for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

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		

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.

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-10993-3 : Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2] ?	☑	☐
FDA Recognition number [3]	# 2-117	
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 tests? 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: Class II Special Controls Guidance Document: Dental Bone Grafting Material Devices

[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 and 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 for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

ISO-10993-3: Biological evaluation of medical devices - Part 3: Tests for genotoxicity

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
014	Biocompatibility test and Performance test reports	☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

OECD Guideline for Testing of Chemicals 471, Genetic Toxicology: Salmonella typhimurium Reverse Mutation Assay

DESCRIPTION

AMES test report number is 2005-MBK-88, tested by Korea Testing and Research Institute for Chemical Industry

JUSTIFICATION

None of the test group showed significant increase in the number of revertant colonies in comparison to the negative control group.

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

Public reporting burden for this collection of information is estimated to average 1 hour 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:

Center for Devices and Radiological Health
1350 Piccard Drive
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 number.

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)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 10993-5 : Biological Evaluation of Medical Devices - Part 5 : Tests for In Vitro Cytotoxicity

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2] ?	☑	☐
FDA Recognition number [3]	# 2-153	
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 tests? 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: Class II Special Control Guidance Document: Dental Bone Grafting Material Devices

[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 and 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 for CDRH Guidance Documents can be found at *www.fda.gov/cdrh/guidance.html*

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ISO 10993-5 Biological evaluation of medical devices-Tests for cytotoxicity: in vitro methods

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
014	Biocompatibility and performance test report	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION
Test report No is 2005-MBK-88, tested by Korea Testing and Research Institute for Chemical Industry

JUSTIFICATION
No cytotoxicity was observed with the test materials.

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.

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Paperwork Reduction Act Statement

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Center for Devices and Radiological Health
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)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 10993-6 : Biological Evaluation of Medical Devices - Part 6 : Tests for Local Effects after Implantation

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA[2]?	☑	☐
FDA Recognition number[3] # 2-120		
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 tests? 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: Class II Special Controls Guidance Document : Dental Bone Grafting Material Devices

[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 and 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 for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

ISO 10993-6 : Biological Evaluation of Medical Devices - Part 6 : Tests for Local Effects after Implantation

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
014	Biocompatibility and Performance test reports	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

Test report No is SNUH-MDEC 050402301, tested by Clinical Research Institute Seoul National University Hospital

JUSTIFICATION

Both control and test group did not exhibit biological responses which defined to ISO 10993-6 requirements.

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.

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Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 10993-10 : Biological Evaluation of Medical Devices - Part 10 : Tests for Irritation and Delayed - Type Hypersensitivity

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2] ?	☑	☐
FDA Recognition number [3] # 2-152		
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 tests? 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: Class II Special Controls Guidance Document : Dental Bone Grafting Material Devices

[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

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

ISO 10993-10, Maximization test for delayed hypersensitivity,Tests for irritation and delayed-type hypersensitivity

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
014	Biocompatibility and Performance test report	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

Skin Sensitization test report No is 2005-MBK-88, tested by Korea Testing and Research Institute for Chemical Industry

JUSTIFICATION

The extracts did not induce any allergic reactions.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
014	Biocompatibility and Performance test report	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

Intracutaneous Reactivity Test report number is 2005-MBK-88, tested by Korea Testing and Research Institute for Chemical Indus

JUSTIFICATION

No skin reactions were noted at the injection sites of both test and control groups of rabbits during 72 hours.

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 10993-11 : Biological Evaluation of Medical Devices - Part 11 : Tests for systemic toxicity.

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2] ?	☑	☐
FDA Recognition number [3]	# 2-118	
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 tests? 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: Class II Special Controls Guidance Document : Dental Bone Grafting Material Devices

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

ISO 10993-11 Biological evaluation of medical device- Part 11: Tests for systemic toxicity.

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
014	Biocompatibility and Performance test reports	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

Acute Systemic Injection test report number is 2005-MBK-88, tested by Korea Testing and Research Institute for Chemical Indust

JUSTIFICATION

None of the tested animals exhibited abnormal clinical signs indicative of toxicity.

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]

ASTM F1980-99 : Standard Guide for Accelerated Aging of Sterile Medical Device Packages

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☐	☑
FDA Recognition number [3] # _____		
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 tests? 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: Class II Special Controls Guidance Document : Dental Bone Grafting Material Devices

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

ASTM F1980-99 : Standard Guide for Accelerated Aging of Sterile Medical Device Packages

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
012	Sterility test report	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

Accelerated stability test report number is 100512-1, tested by Nibcc

JUSTIFICATION

The result of the test have met ASTM F1581-99 requirements.

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]

ASTM F1581-99 : Standard Specification for Composition of Anorganic Bone for Surgical Implants

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA[2]?	☐	☑
FDA Recognition number[3] # _____		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
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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 tests? 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: Class II Special Controls Guidance Document : Dental Bone Grafting Material Devices

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

ASTM F1581-99 "Standard Specification for Composition of Anorganic Bone for Surgical Implants"

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
016	Clinical data	☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

Compared OCS-B with other products and found that OCS-B is considered to be safe and effective for use as a Bone Graft.

JUSTIFICATION

Annex 7-2. Comparison table with other devices.

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 11137-1:2006, Sterilization of health care products - Radiation - Part 1: Requirements for development, validation, and routin

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3]	# 14-297	
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.	☑	☐
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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?	☑	☐

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

ISO 11137-1:2006, Sterilization of health care products - Radiation - Part 1: Requirements for development, validation, and routin

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
012	Sterility Validation Test Report (Bowl)	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

Gamma Sterilization Validation for the Medical Device (Bowl)

DESCRIPTION

Test report NO 090609

JUSTIFICATION

Met the requirement standard ISO 11137-1 met

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
012	Sterility Validation Test Report (Vial)	☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

Gamma Sterilization Validation for the Medical Device (Vial)

DESCRIPTION

Test report NO 101005-1

JUSTIFICATION

Met the requirement standard ISO 11137-1 met

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
012	Sterility Validation Test Report (Syringe)	☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

Gamma Sterilization Validation for the Medical Device (Syringe)

DESCRIPTION

Test report NO 110509-1

JUSTIFICATION

Met the requirement standard ISO 11137-1 met

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 11137-2:2007, 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] # 14-225		
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 tests? 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: Class II Special Controls Guidance Document : Dental Bone Grafting Material Devices

[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 and 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 for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

ISO 11137-2:2007, Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Sterility validation	Sterility Validation Test Report	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

Studies on Dos Audit For Gamma Steriliation

DESCRIPTION

Test report NO 2009-1012

JUSTIFICATION

Met the requirement standard ISO 11137-2 met

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

Public reporting burden for this collection of information is estimated to average 1 hour 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:

Center for Devices and Radiological Health
1350 Piccard Drive
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 number.

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)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 11137-3 : Sterilization of Health Care Products - Radiation - Part 3 : Guidance on Dosimetric Aspects

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2] ?	☑	☐
FDA Recognition number [3]	# 14-298	
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 tests? 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: Class II Special Controls Guidance Document : Dental Bone Grafting Material Devices

[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 and 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 for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

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		
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

Public reporting burden for this collection of information is estimated to average 1 hour 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:

Center for Devices and Radiological Health
1350 Piccard Drive
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 number.

Attachment 12 : 510(k) Summary

12.0 510(k) Summary

[as required by 807.92(c)]

Sponsor/Applicant

NIBEC Co., Ltd.

Iwol electricity-electronic Agro-industrial Complex, 1127, Sinwol-ri,

Iwol-myeon, Jincheon-gun, Chungcheongbuk-do, Korea

Phone : 82-10-2889-8590

Fax : 82-2-744-8732

Contact : Dr. Park, Yoon-Jeong

Date Prepared : April 4, 2012

Device Name and Identification

Proprietary Name : OCS-B™

Common / Usual Name : Natural Bone Mineral Matrix

Anorganic Bovine Bone Grafting Material

Classification Name : Bone Grafting Material

Animal Source Dental Bone Grafting Material

Predicate Device

Bio-Oss® natural bone grafting material (K871773, K952617, K970321, K033815)

Manufactured by :

Geistlich Pharma AG

Bahnhofstrasse 40

CH-6110 Wolhusen

Switzerland

Device Category/Class

Device Class : Class II

Regulation Number : 21 C.F.R. 872.3930

Product Code : NPM

Indication for use

OCS-B™ cancellous and cortical granules are recommended for:

- Augmentation or reconstructive treatment of the alveolar ridge.
- Filling of infrabony periodontal defects.
- Filling of defects after root resection, apicoectomy, and cystectomy
- Filling of extraction sockets to enhance preservation of the alveolar ridge
- Elevation of maxillary sinus floor
- Filling of periodontal defects in conjunction with products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR)
- Filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration (GBR)

Device Description

OCS-B™ is a sterile, natural, non-antigenic, porous bone mineral matrix produced by the removal of organic compounds from bovine bone. Due to its natural structure OCS-B™ is physically and chemically comparable to the mineralized matrix of human bone. The anorganic bone matrix of OCS-B™ has a macro and microporous structure similar to human bone. The formation and in-growth of new bone at the implantation site of OCS-B™ is favored due to its trabecular architecture, interconnecting macro and micro pores, and its natural consistency. It is supplied as cancellous (spongiosa) or cortical granules in a single use container, packaged in a secondary thermoform blister, and sterilized by γ-irradiation.

Basis for Substantial Equivalence

OCS-B™ and Bio-Oss® have a similar physical and chemical structure. Both are porous, biocompatible bone grafts that facilitate the formation and mineralization of new bone by the osteoblast. The primary difference between the two products is the source bone : OCS-B™ is manufactured from bovine (cows) bones, while Bio-Oss® is manufactured from bovine(cows) source material.

The following table summarizes the basis for the Sponsor's substantial equivalence determination :

Table 1 Substantial Equivalence Comparison

ITEM	OCS-B™	Bio-Oss®
Intended Use	Used as an adjective therapy in restoring bony defects	Used as an adjective therapy in restoring bony defects
Target population	Human Oral, Periodontal	Human Oral, Periodontal
Dosage form	Granules contained in single use container	Granules contained in single use container
Granule sizes	0.2mm to 1.0mm or 1.0mm to 2.0 mm granules	0.25mm to 1.0mm or 1.0mm to 2.0 mm granules
Material	Anorganic naturally derived osteoconductive hydroxyapatite bone mineral	Anorganic naturally derived osteoconductive hydroxyapatite bone mineral
Source bone	Bovine bone	Bovine bone
Physical Morphology	Trabecular, interconnecting macro and micro pores	Trabecular, interconnecting macro and micro pores
Biocompatibility	Biocompatible, as demonstrated by : - Genotoxicity testing - Intracutaneous reactivity testing - Maximization and sensitization testing - Pyrogen testing - Acute systemic injection testing - Cytotoxicity testing	Biocompatible (as demonstrated in published literature)

	- Implantation testing - Preclinical safety and efficacy testing - Clinical case series	
Performance	Bone formation	Bone formation
Compatibility w/other devices	Can be used with GTR membrane	Can be used with GTR membrane
Sterilization Process	Sterile by Gamma irradiation	Sterile by Gamma irradiation
Chemical Composition	Similar to Bio-Oss® based on chemical analysis, XRD, FT-IR and ICP analysis	Similar to OCS-B™ based on chemical analysis, XRD, FT-IR and ICP analysis
Chemical safety	Biocompatible	Biocompatible
Anatomical sites	Oral, Periodontal	Oral, Periodontal
Pyrogen Free	Yes	Yes
Shelf life	3 years	Determined by Manufacturer

Brief Summary of Data Submitted in Support of Effectiveness

The Sponsor evaluated the performance characteristics of OCS-B™ and Bio-Oss® with a thorough chemical and physical characterization. The physical and chemical characteristics of the products were found to be comparable. Further, in several animal studies, both products were found to grow new bone and be s ubsequently resorbed at similar rates. Finally, in a clinical case series, use of OCS-B™ resulted in defect healing and formation of new bone of sufficient quality to obtain dental implant placement.

Brief Summary of Data Submitted in Support of Safety

OCS-B™ was the subject of the full range of biocompatibility tests recommended in the FDA's "Class II. Special Controls Guidance Document: Dental Bone Grafting Devices" and in accordance with ISO 10993. Test results confirmed product safety. Organic material has been removed from the product, and product specifications have been established to limit protein content. Further, the product is sterilized to achieve a sterility assurance level SAL 1 x 10^{-6}.

Based on the information presented herein, it has been demonstrated that OCS-B™ is

substantially equivalent to Bio-Oss® , and safe and effective for the proposed indications for use.

K113246/S3

DEPARTMENT OF HEALTH & 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

V.1

December 14, 2012

NIBEC COMPANY, LIMITED
C/O PATS CORP.
4568 W. 1ST STREET
SUITE 104
LOS ANGELES, CALIFORNIA 90004
ATTN: DANIEL NAM

510k Number: K113246
Product: OCS-B
On Hold As of 12/12/2012

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm.

In accordance with 21 CFR 807.87(l), FDA may consider a 510(k) to be withdrawn if the submitter fails to provide additional information within 30 days of an Additional Information (AI) request. FDA generally permits submitters additional time to respond to such requests. FDA intends to automatically grant a maximum of 180 calendar days from the date of the AI request, even if the submitter has not requested an extension. Therefore, submitters are no longer required to submit written requests for extension. However, submitters should be aware that FDA intends to issue a notice of withdrawal under 21 CFR 807.87(l) if FDA does not receive, in a submission to the appropriate Document Control Center, a complete response to all of the deficiencies in the AI request within 180 calendar days of the date that FDA issued that AI request. In this instance, pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

For further information regarding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee Amendments of 2012 (MDUFA III), to the Federal Food, Drug, and Cosmetic Act, you may refer to our guidance document entitled "Guidance for Industry and Food and Drug Administration Staff - FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals". You may review this document at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm>.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

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

Napperli, Jesse *

From: Napperli, Jesse *
Sent: Friday, December 14, 2012 9:48 AM
To: 'PATS0433@YAHOO.COM'
Subject: K113246 HOLD LETTER
Attachments: CrystalViewerCAC9J41Y.rtf

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Lauren Giles

Subject: 510(k) Number K113246/S3

To: The Record

Please list CTS decision code _____

- ☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207202%2007.doc)
- ☐ Hold (Additional Information or Telephone Hold).
- ☐ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

☐	NO	NSE for lack of predicate
☐	NI	NSE for new intended use
☐	NQ	NSE for new technology that raises new questions of safety and effectiveness
☐	NU	NSE for new intended use AND new technology raising new questions of safety and effectiveness
☐	NP	NSE for lack of performance data
☐	NS	NSE no response
☐	NL	NSE for lack of performance data AND no response
☐	NM	NSE pre-amendment device call for PMAs (515i)
☐	NC	NSE post-amendment device requires PMAs
☐	NH	NSE for new molecular entity requires PMA
☐	TR	NSE for transitional device

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*		
510(k) Summary /510(k) Statement	*Attach Summary*		
Truthful and Accurate Statement.	*Must be present for a Final Decision*		
Is the device Class III?			
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			
Is clinical data necessary to support the review of this 510(k)?			
For United States-based clinical studies **only**: Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If study was			

conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)

Does this device include an Animal Tissue Source?

All Pediatric Patients age<=21

Neonate/Newborn (Birth to 28 days)

Infant (29 days -< 2 years old)

Child (2 years -< 12 years old)

Adolescent (12 years -< 18 years old)

Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)

Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)

Nanotechnology

Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html) *Contact OC.*

Regulation Number	**Class***	**Product Code**

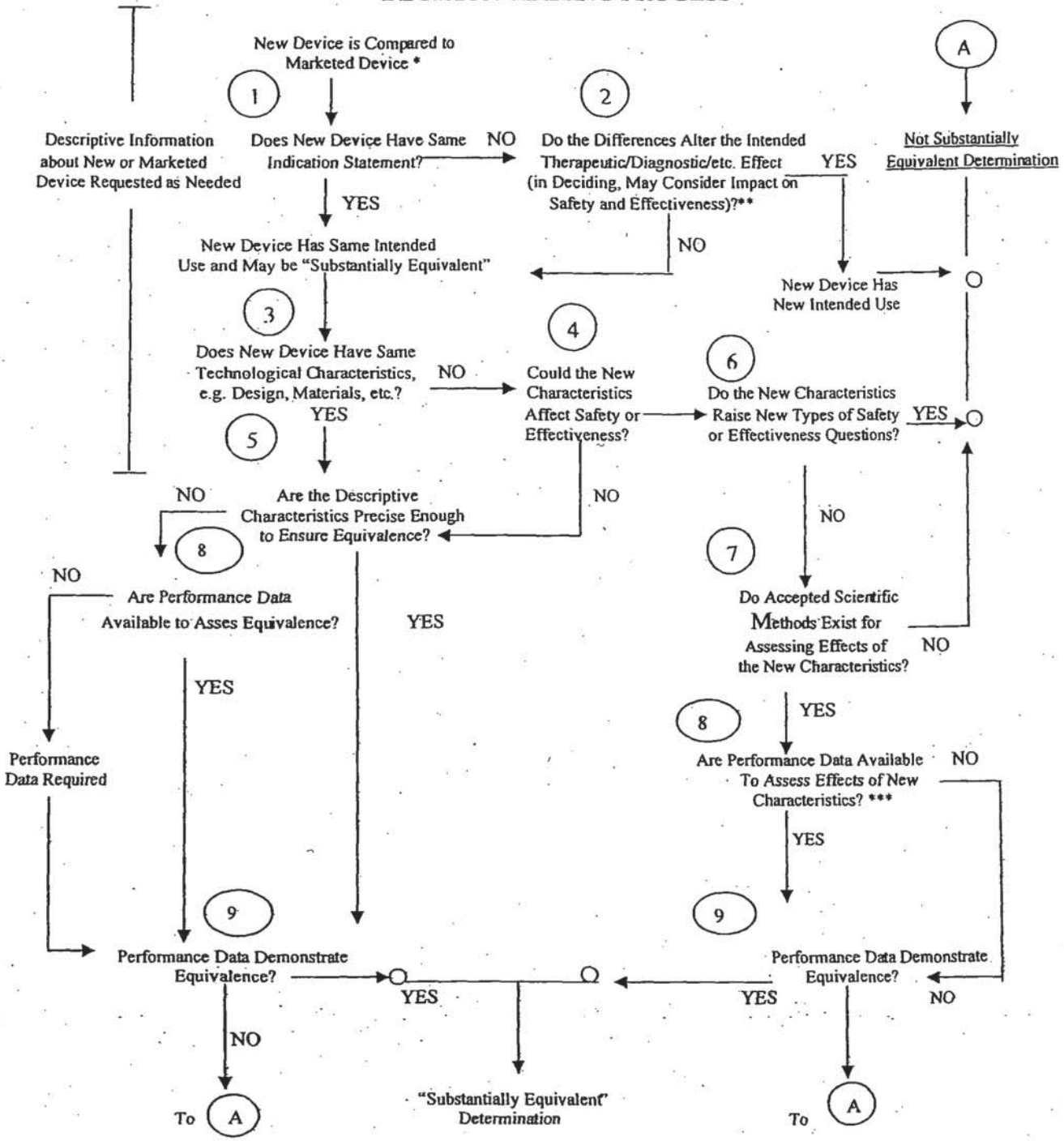
(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: Susan Runner (Branch Chief) DEND (Branch Code) 12/13/12 (Date)

Final Review: For Susan Runner (Division Director) 12/13/12 (Date)

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

DEPARTMENT OF HEALTH AND HUMAN SERVICES MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Premarket Notification [510(k)] Review
Traditional

Telephone Hold #2

K113246/S002

Date: December 12, 2012

To: The Record Office: ODE

From: Lauren Giles, Biomedical Engineering Division: DAGID

510(k) Holder: NIBEC Co., Ltd., of Chungcheongbuk-do, Korea
Device Name: *OCS-B* (K113246/S002)
Contact: Mr. Daniel Nam
Phone: 1-213-626-1544
Fax: 1-213-626-1548
Email: Pats0433@yahoo.com

I. Purpose and Submission Summary

NIBEC Co., Ltd., of Chungcheongbuk-do, Korea, has submitted a Premarket Notification (510(k)) to introduce into U.S. interstate commerce *OCS-B,* an organic bovine bone filling material. *OCS-B* is a prescription Class II medical device regulated under 21 CFR 872.3930 as a "Bone Grafting Material." The *OCS-B* is listed under product code NPM.

The submission for *OCS-B* consists of Form FDA 3674, Form FDA 3514, 510(k) Cover Letter, Truthful and Accurate Statement, Indication for Use, Safety and Effectiveness Statement, Screen Checklist, FDA Form 3674, Form 3654, Label and Package, User Manual, Product Description, Sterility Validation Report, Substantial Equivalence Report, Biocompatibility and Performance Test report, Risk Analysis Report, Clinical data, 510(k) Summary, Viral Inactivation report.

The primary mode of action for this device is grafting to dental defect to promote bone growth. The submission claims substantial equivalence to *BIO-OSS, BIO-OSS BLOCKS and BIO-OSS Collagen* (K033815).

The submission references the following standards in Form FDA 3514 but has provided Form FDA 3654 for all standards referenced.

Standard	Standard Title	Version
IEC 980	Graphical symbols for use in labeling of medical devices	2003
IEC 1041	Information supplied by the manufacturer with medical devices	1998
ISO 10993-1	Biological evaluation of medical devices – Part 1: Evaluation and Testing	2003
ISO 10993-5	Biological evaluation of medical devices – Part 5: Test for In Vitro Cytotoxicity	
ISO 10993-10	Biological evaluation of medical devices – Part 10: Test for irritation and delayed-type hypersensitivity	2002
ISO 10093-11	Biological evaluation of medical devices – Part 11: Test for system toxicity	2002
ISO 10093-6	Biological evaluation of medical devices – Part 6: Test for local effects after implantation	2007
ISO 14971	Medical Devices – Application of risk management to medical devices	2007

Reviewer's Notes:

- *In Form FDA 3514 the applicant lists the device classification as unknown; in addition on page 52 of the submission the applicant lists the device classification as Class III. However, under the NPM product code, the proposed device is consider Class II and contains special controls and FDA issued guidance document for "Dental Bone Grafting Material" and "Medical Devices Containing Materials Derived for Animal Sources."*
- *Form FDA 3654 has not provided for all the standards listed in Form FDA 3514. In addition, the submission references to several other standards on page 52 of the submission and in the sterilization and performance testing reports. Form FDA 3654 should be provided for all standard referenced or relied on in this submission.*

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription)			
(Indicate if: OTC)			
Truthful and Accuracy Statement			
Standards Form			

	YES	NO	N/A
Required Elements for 510(k) Summary (21 CFR 807.92)			
Clearly labeled "510(k) Summary"	X		
Submitter' s name, address, phone #, a contact person		X	
Date the summary was prepared		X	
The name of the device/trade name/common		X	

			YES	NO	N/A
	name/classification name				
	An identification of the legally marketed Predicate		X		
	Description of the subject device			X	
	Statement of intended use(identical to indications for use)		X		
	Technological	if same, a summary of comparison of technological characters		X	
		If different, a summary of how do they compare to the Predicate		X	
	Performance Data	Brief discussion of non-clinical data submitted, referenced, or relied on		X	
		Brief discussion of clinical data submitted, referenced, or relied on, including: ▪ Description upon whom the device was tested, ▪ Data obtained from the tests and especially: ▪ Adverse events and complications ▪ Other information for SE determination		X	
		Conclusion that data demonstrate SE		X	
Required Elements for <u>510(k) Statement</u> (21 CFR 807.93)					
	Signed verbatim statement		X		

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?	X		
Does the device design use software?		X	
Is the device sterile?	X		
Is the device reusable (not reprocessed single use) and are "cleaning" instructions included for the end user?		X	

OCS-B is an anorganic xenogeneic bone grafting material. *OCS-B* is composed of bovine natural hydroxyapatite derived for Korean native cattle bone. OCS-B is provided in three types: a vial, bowl, or syringe. All three types are supplied as cancellous granules or cortical granules. The

particle size of *OCS-B* ranges from 0.212mm to 2.0mm. The Ca/P ratio of *OCS-B* is 1.66.

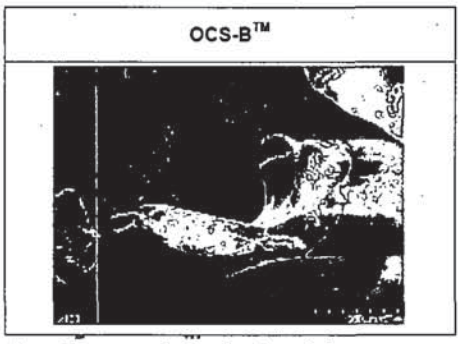
The device description includes a step-by-step flow chart and narrative of the manufacturing process for *OCS-B*. The raw material is soaked twice in purified water for 6-15 hours. The material is then heated for no more than 6 hours a day and washed of the fatty/flesh substance and dried for 12 hours at 120°C. The dried bovine bone is then classified as either cancellous or cortical and crushed. The crushed particles are soaked on methanol, chloroform, and sodium hypochlorite followed by washing in purified water. The material is then tested for the presence of proteins using a protein assay. If no proteins are detected the material passes. The material is then tested using a pH assay; if the material passes it is placed in a sieve for crushing to the desired particle size.

The risk analysis also provides addition details of *OCS-B*. *OCS-B* is produced only using the apatite component from the bovine thigh bone and is intended for direct implantation into the bony defect. It is intended to have a 3-6 month healing period where 30-50% of the granules are absorbed into the tissue.

Reviewer's Notes:

- *Korea is not listed on the FDA guidance document for "Medical Devices Containing Material Derived from Animal Source" as a country which BSE exist or presents a significant risk.*
- *The submission does not include any details on the chemical composition by weight or molar weight for the proposed device. In addition no details can be found on the raising, feeding, vaccination of the cattle.*
- *The submission does not specify the protein assay and what proteins are being tested.*

In S2, the applicant provided additional information to characterize the chemical and physical properties of OCS-B. OCS-B is an inorganic bone material primary composed of B-type hydroxyapatite. OCS-B is marketed as 0.2mm to 1.0mm and 1.0mm to 2.0mm granules in a variety of fill sizes. The degree of crystallization was tested by FT-IR and found to be below the commercial Low Crystalline Hydroxyapatite standard and primarily amorphous > 95%.



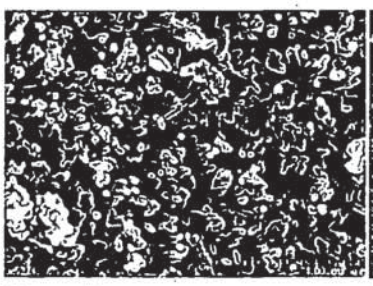


Figure 2
Low crystalline HAp(Aldrich)

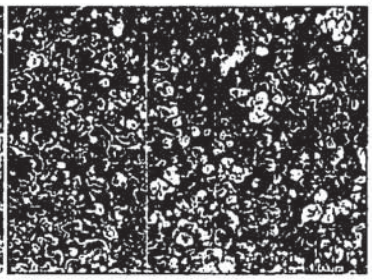


Figure 3
O CS-B™ (NIBEC Co., Ltd.)

An elemental analysis of the proposed device and predicate are provided below.

Test Item	OCS-B™ (lot# B101144)		Bio-Oss® (lot# 090245)	
	Unit	Result	Unit	Result
Pb	%	0	%	0
Cd	%	0	%	0
Ca	%	38.2000	%	38.1403
Mg	%	0.3666	%	0.3672
Na	%	0.3669	%	0.4391
Zn	%	0.0083	%	0.0075
P	%	17.6100	%	17.5260
Hg	%	0	%	0

Table 6 Specification for the Release of the Bulk Granules

Title	Method	Requirement
pH Test	pH measurement	pH of 7.0 ± 1.5
Protein assay (Deprotenization between thermal treatment Process)	Bradford assay	< 135 ppm

Table 7 Specification for the Release of the Final Product

Title	Method	Requirement
Appearance of product	Sealing condition, particle presence in the designated specification	White particulates in the sealed vial/bowl/syringe in the blisters
Appearance of granules	Particle size : ISO3310-1	> 90% of stated range (wt%)
	Weight variation : total weight of granules within be the container.	0.1g, 0.25g ± 20% 0.5g, 1g, 2g, 5g ± 10%
Water content	USP	< 5% (by wt%)
Label	Macrography (visual)	Check required label, and label condition
Protein assay	Bradford assay	< 135 ppm
Heavy Metals (as Pb)	USP	< 0.002%
Sterility	USP	Sterile
Bacterial Endotoxins(LAL)	USP	< 20.0 USP EU/vial

IV. Indications for Use

OCS-B® is recommended for:

- Augmentation or reconstructive treatment of the alveolar ridge.
- Filling of infrabony periodontal defects.
- Filling of defects after root resection, apicoectomy, and cystectomy.
- Filling of extraction sockets to enhance preservation of the alveolar ridge.
- Elevation of the maxillary sinus floor.
- Filling of periodontal defects in conjunction with products intend for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR).
- Filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration (GBR).

Reviewer's Notes:
The IFUS provided in the submission is not marked for prescription use. The IFUS is identical in wording and content to the declared predicate device.

V. Labeling

The submission includes draft labeling for the packaging and also contains draft Instructions for Use.

The *OCS-B* products contain several packaging labels including a Tyvek label, paper box, and outer carton box. The labeling include a product description (trade name, particle size, granule type, and weight), the manufacturer information, sterile, single use only, caution to read instructions, lot and expiration date, and the prescription statement as required by 21 CFR 801.109. The labeling contains no symbols and all text is written in the English language.

The submission also includes draft Instructions for Use. The main insert state that *OCS-B* should only be placed in well vascularized bone. *OCS-B* can be mixed with autogenous bone, osseous coagulum, patient's blood or sterile normal saline. For larger defects it should be mixed with autogenous bone in a 1:1 ratio. *OCS-B* should be placed with light/moderate pressure and the defects should not be overfilled. The instructions state the graft site should be allowed to heal for 6 months prior to implant placement.

In addition to the main insert, each type (vial, bowl, and syringe) of *OCS-B* contains directions. These direction include sections for Components and Characteristics, Uses, Instructions, Contraindications, Adverse Reactions, How Supplied, and Storage. The Instructions are similar to that in the main insert. The proposed device is contraindicated for use in people with metabolic diseases, liver disease, and vascular impairment among others. The "How Supplied" section details the all the variations of the granule, weight, and size of *OCS-B* provided for each type (vial, bowl, and syringe). *OCS-B* is to be stored at room temperature.

Reviewer's Notes:

- *The "Components and Characteristics" sections of the directions contain the following unsubstantiated claims:*
  - *"OCS-B is free of organic impurities including inflammatory proteins, lipid, and provides similar nanocrystal structure to human bone."*

- *"OCS-B facilitates osteoconduction due to its 3-dimensional porous structure and helps mineralization process."*

- *The Uses section should be revised to state "Intended Use." The Intended Use should be identical to the Indications for Use Statement provided in the submission.*
- *The "Instructions" sections of the directions contain the following unsubstantiated claims:*
  - *"Mixing OCS-B cancellous granules and OCS-B cortical granules in a ratio of 1:1 in bone regeneration procedure may result in elevating the strength of new bone."*

VI. Sterilization/Shelf Life/Reuse

(b)(4)

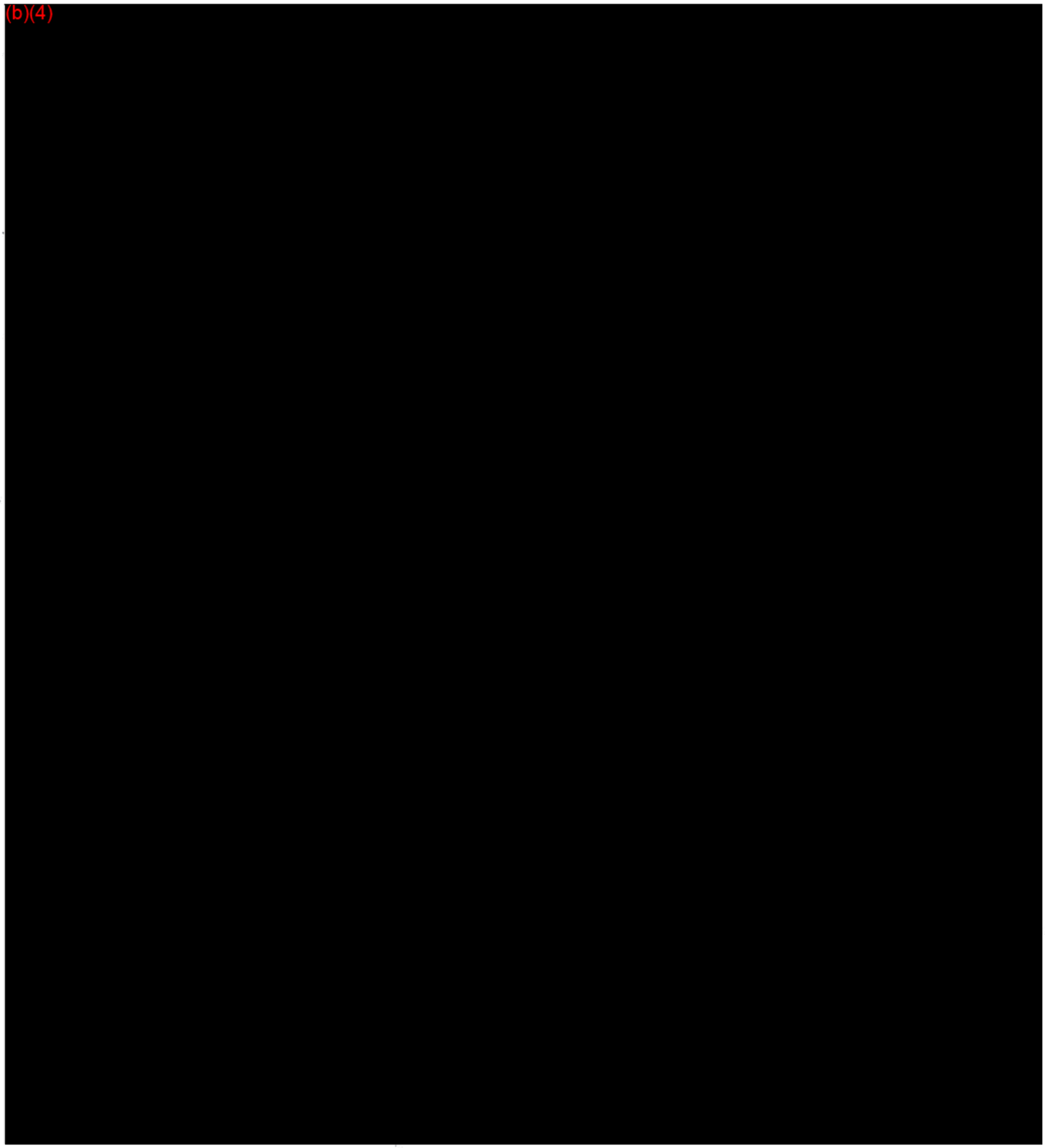
[redacted]

VII. **Biocompatibility**

(b)(4)

[redacted]

(b)(4)



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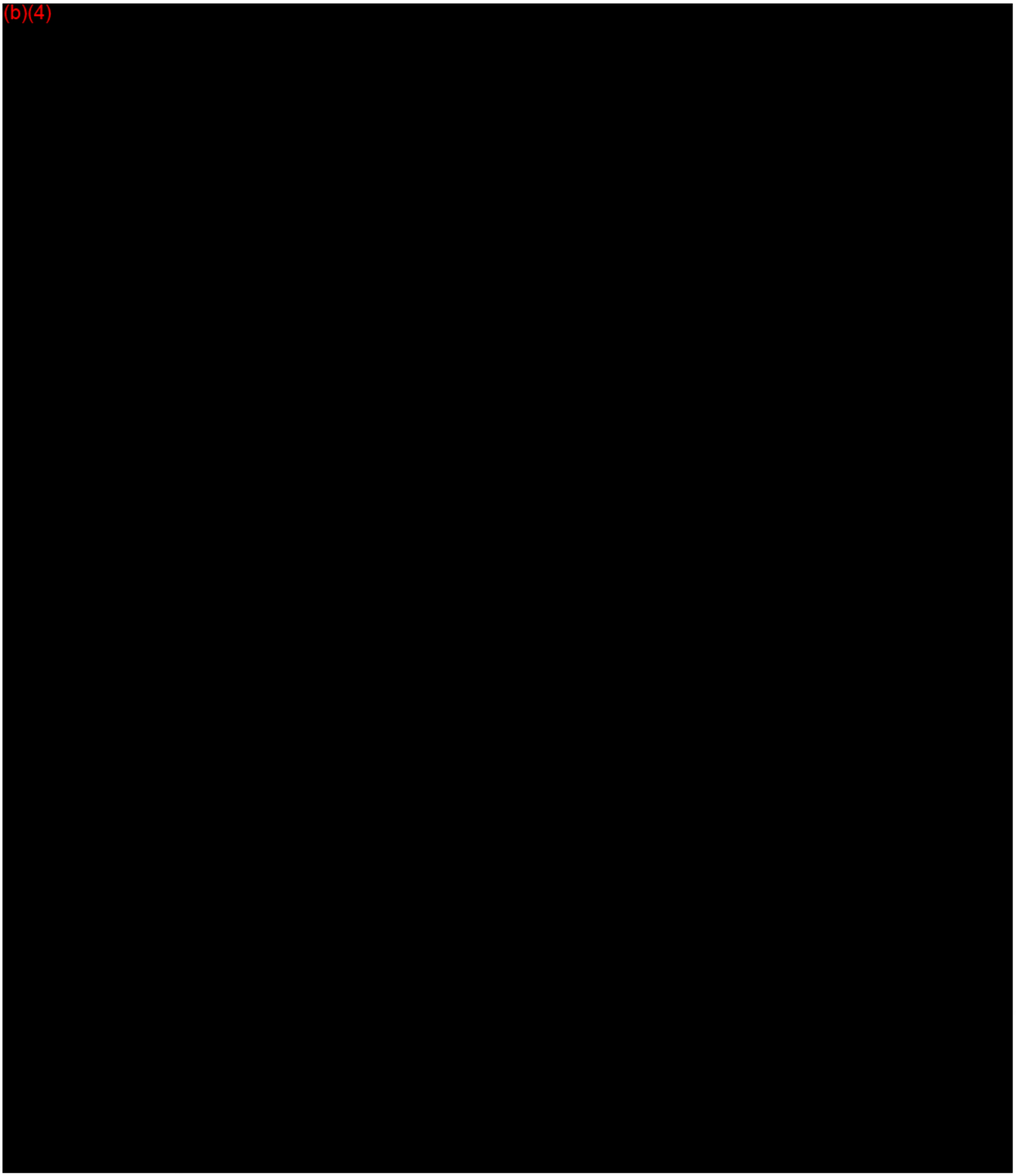

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[redacted]

VIII. Software

OCS-B does not appear to contain any software as defined in the scope of FDA's "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". Therefore, software documentation and validation is not required for *OCS-B*.

IX. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

OCS-B does not appear to produce an EM field, utilize electricity, or produce a thermal effect. Therefore, EMC, electrical safety, and thermal safety are not applicable.

X. Performance Testing – Bench

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[redacted]

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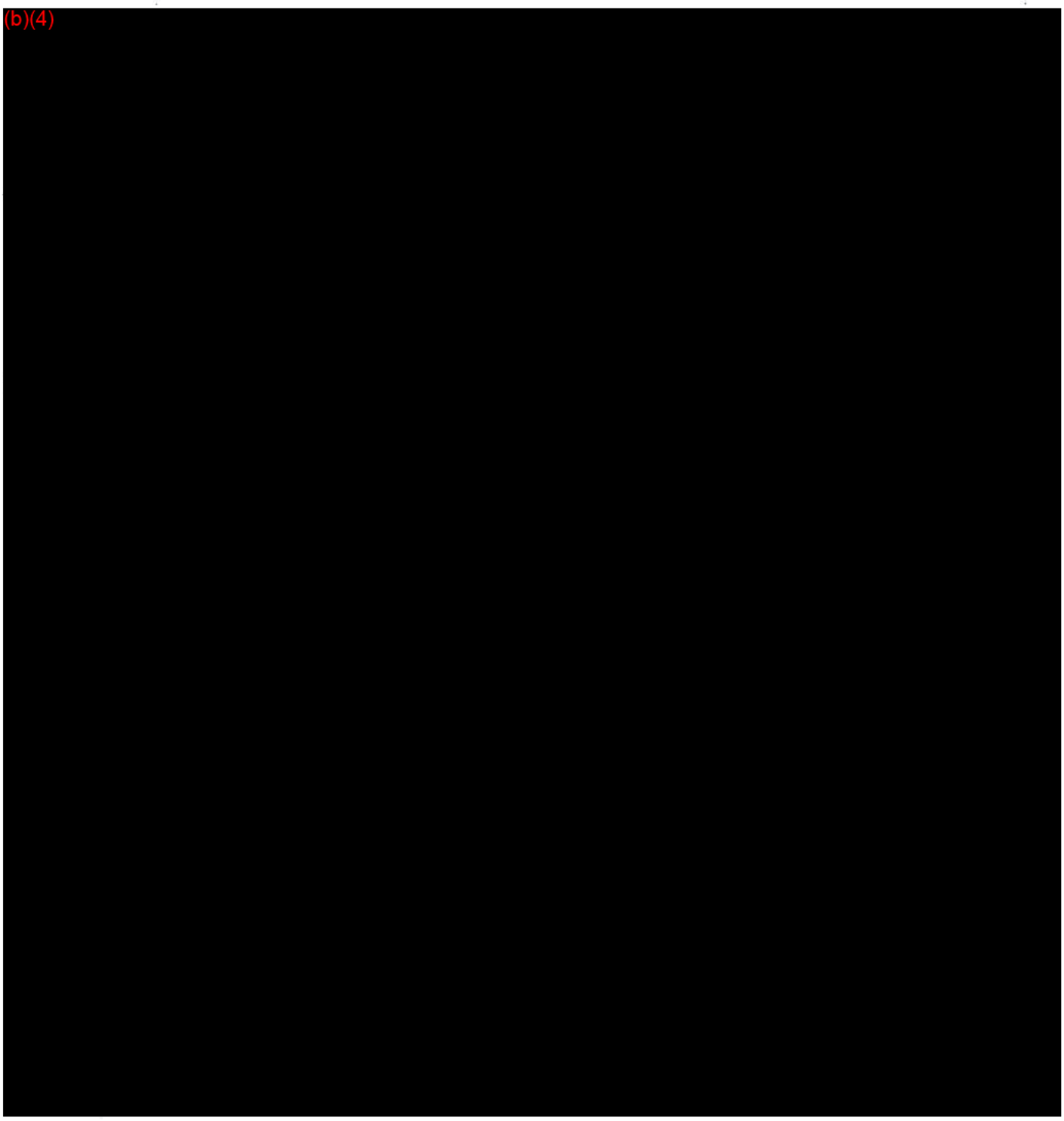

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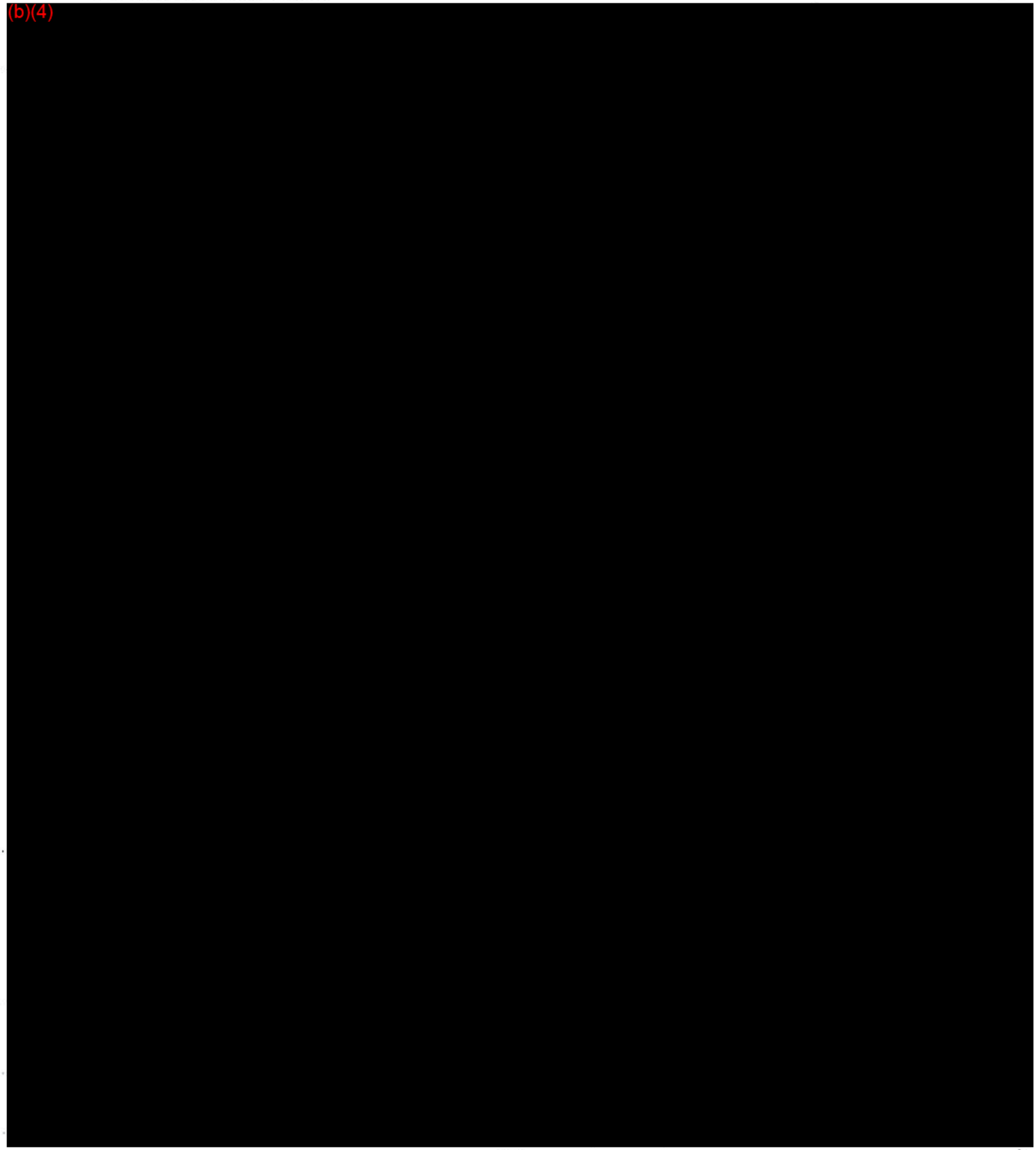

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XI. Performance Testing – Animal

(b)(4)

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[redacted]

XII. Performance Testing – Clinical

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[redacted]

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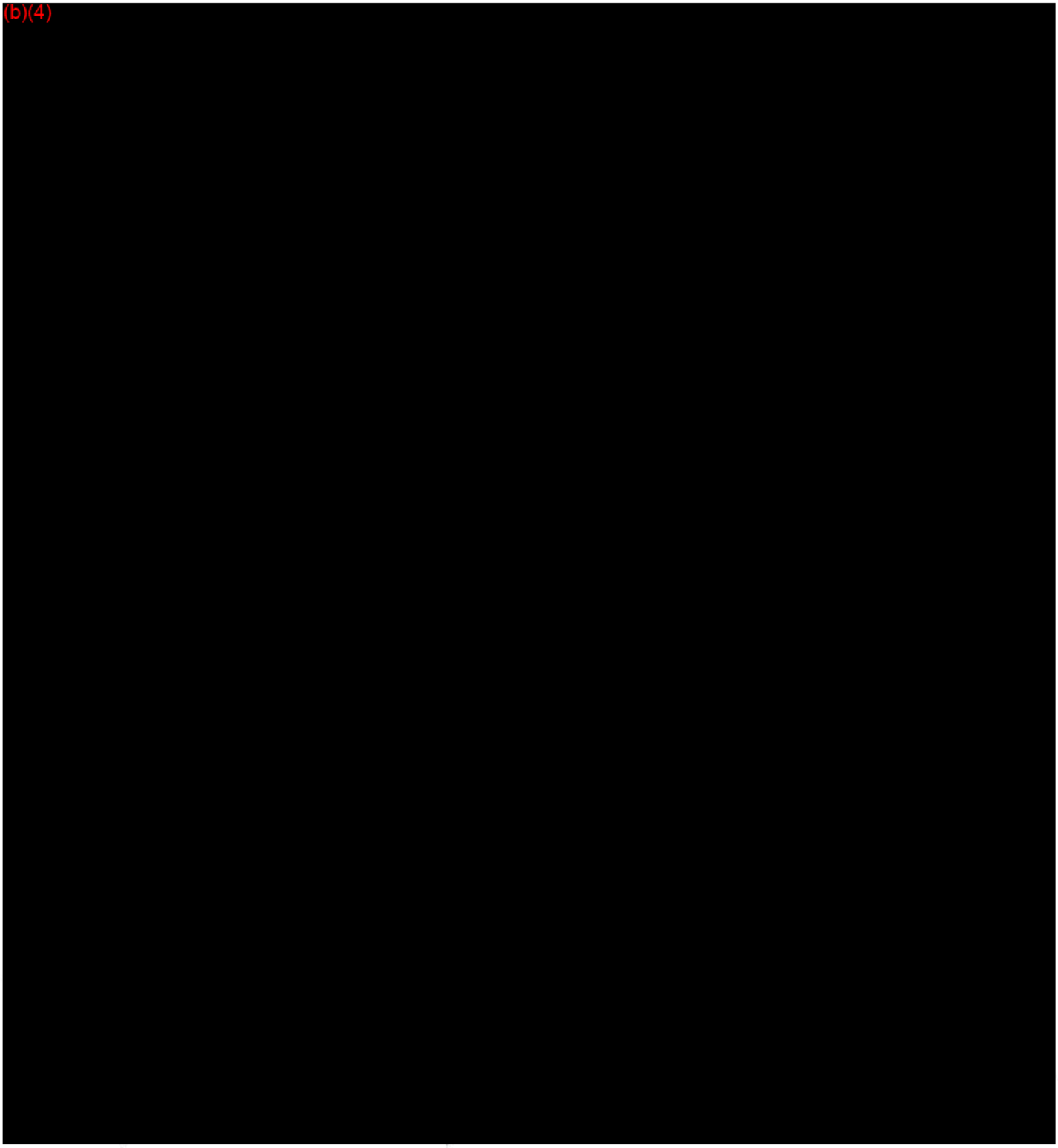

XIV. Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?			If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
3. Same Technological Characteristics?			If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?			If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
8. Performance Data Available?			If **NO** = Request Data
9. Data Demonstrate Equivalence?			Final Decision:

Note: See http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:
2. Explain why there is or is not a new effect or safety or effectiveness issue:
3. Describe the new technological characteristics:
4. Explain how new characteristics could or could not affect safety or effectiveness:
5. Explain how descriptive characteristics are not precise enough:
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
7. Explain why existing scientific methods can not be used:
8. Explain what performance data is needed:
9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

XV. Deficiencies

(b)(4)

[redacted]

(b)(4)

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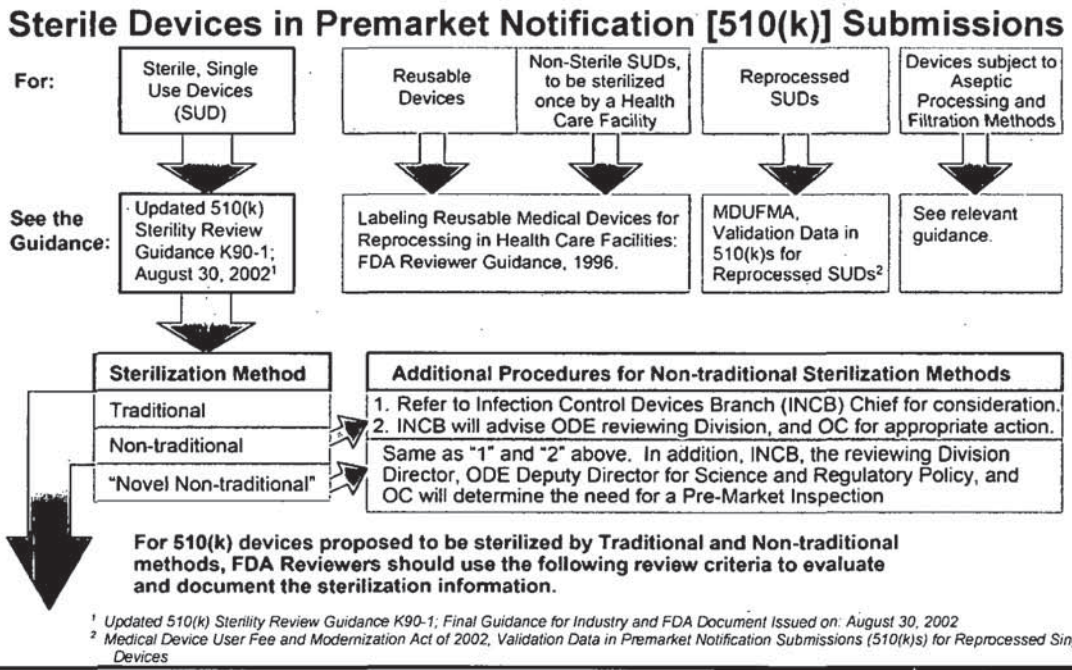
XVI. Recommendation

Telephone Hold.

Digital Signature Concurrence Table	
Reviewer Sign-Off	Lauren M. Giles 2012.12.13 01:10:44 -05'00'
Branch Chief Sign-Off	2012.12.13 Susan Runner DDS, MA 07:15:02 -05'00'



1. Sterilant:	YES	NO
a. **Sterilization method** description (e.g., Steam, EtO, Radiation):	Gamma Radiation	
b. **Dose**, for radiation	25kGy	

(e.g., 25 – 40 kGy):		
c. **Sterilant residuals** remaining on the device: For EO, the maximum levels of residuals of EO and ethylene chlorhydrin that remain on the device (note: not to include ethylene glycol residual level because the recognized standard, "ANSI/AAMI/ISO 10993-7:1995 Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide sterilization residuals," does not include measurement of ethylene glycol residuals);	N/A	
2. A description of the Validation Method for the sterilization cycle (not data): (Citation of an FDA recognized standard is acceptable (e.g., ANSI/AAMI/ISO 11135))	ISO 11137-1,-2 VDMax	
3. Sterility assurance level (SAL): (e.g., 10^{-6} for all devices (except 10^{-3} for devices that contact intact skin))	10^{-6}	
4. Is it labeled "Pyrogen Free"?	??	
If so, a description of the method: (e.g., LAL (*Limulus* Amebocyte Lysate test))		
5. A description of the packaging (not including package integrity test data):	See memo Sec. VI	

Giles, Lauren

From: Giles, Lauren
Sent: Thursday, December 13, 2012 1:09 AM
To: 'Pats0433@yahoo.com'
Subject: OCS-B (K113246) Additional Information Request and Telephone Hold

Mr. Nam,

I have been assigned to the review of *OCS-B (K113246)*. After continued review of your submission, I have come across the following deficiency in the submission that should be addressed.

(b)(4)

[redacted]

(b)(4) [redacted]

I am available to review any information you are considering before its official submission in order to ensure that it fulfills these requests.

I am placing this document on telephone hold pending the submission of information in response to these requests and the determination that this information fulfills each request. In order to remove this document from its hold status, you must submit this information in hard copy to the Document Mail Center at the same address to which your original submission was sent. In addition, please send an electronic copy of your response to me via email. I am available to review any information you are considering before its official submission in order to ensure that it fulfills these requests.

Please contact me with questions or concerns.

Sincerely,

Lauren Giles
Biomedical Engineer/Reviewer
FDA/ODE/DAGRID/DEDB
10903 New Hampshire Avenue
WO66 - Rm. 2546
Silver Spring, MD 20993
one: 301-796-9552
Fax: 301-847-8109
Lauren.Giles@fda.hhs.gov

DEPARTMENT OF HEALTH & 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

December 06, 2012

NIBEC COMPANY, LIMITED
C/O PATS CORP.
4568 W. 1ST STREET
SUITE 104
LOS ANGELES, CALIFORNIA 90004
ATTN: DANIEL NAM

510k Number: K113246

Product: OCS-B

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

Wilson, Kevin *

m: Wilson, Kevin *
ent: Thursday, December 06, 2012 12:23 PM
To: 'GIC4USA@YAHOO.COM'
Subject: K113246 AI LETTER

CrystalViewerCA...

K5 K113246/S3

PATS corp.
CERTIFICATION BUSINESS

4568 W. 1st Street, Suite 104
Los Angeles, CA 90004USA
e-Mail: gic4usa@yahoo.com
Phone: 213-626-1544 FAX: 213-626-1548

Nov 30 2012
Document Mail Center
Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring. MD20993-0002

FDA CDRH DMC
DEC 06 2012
Received

Reference : K113246
Product: OCS-B
Submitter: **NIBEC CO LTD.**
Applicant: PATS CORP
Manufacturer: **NIBEC CO LTD.**

Dear Officer

We got the letter of your requirements regarding the product (**k113246**) since email dated June 16 .
According to your requests, we hereby submit the additional information under listed.
Please check the followings.
Thank you.

Table of Contents

Very truly yours,

Daniel Nam / General Manager
Authorized Agent for 510K Applicant.

November 29, 2012

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

510K Number: K113246
Response to Information Request
Product: OCS-B (bovine derived hydroxyapatite)

To Whom It May Concern:

NIBEC herewith submits in duplicate our response to the deficiencies outlined in Ms. Lauren Giles' email dated June 16 **(see Tabular – Additional FDA Information Request - email dated 6/16/2012)** to 510(k) Number K113246, OCS-B (bovine derived hydroxyapatite). On August 7, the FDA granted additional time to respond to the Information request until August 31, 2012.

We are confident that the responses provided address the concerns raised in Ms Giles' email support Agency clearance of the above-referenced 510(k) notification for OCS-B. We would like to thank the Division for its review of our submission.

****

For ease of review of this submission, data displays and discussion have been incorporated into the responses wherever possible. Where additional data or information is required, it is included as an Attachment.

For the convenience of the reviewer, we repeat below in **BOLD** the deficiencies conveyed by Ms. Lauren Giles, followed by NIBEC's response to each deficiency.

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[redacted]

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(b)(4) [redacted]

If you need further information or have other comments please do not hesitate to contact me. We are looking forward to hearing a favorable response from you. Thank you.

Best wishes,

Yoon Jeong Park, Ph.D.
Manufacturing Quality Manager of NIBEC
E-mail: parkyj@snu.ac.kr
Tel: 82-10-2889-8590

Attachment Lists for the Response letter

Attachment 1 : Vaccination Protocol for Cattle in Korea

Attachment 2 : Report for TSE Inactivation Process Validation

Attachment 3 : Virus Clearance study report

Attachment 4 : Test report for the analysis of residual solvent

Attachment 5 : Risk analysis

Attachment 6 : Cleaning validation report for OCS-B

Attachment 7 : Genotoxicity evaluation report *(In vitro)*

Attachment 8 : Genotoxicity evaluation report *(In vivo)*

Attachment 1 : Vaccination Protocol for Cattle in Korea

Vaccination Protocol for Cattle in Korea

Item	Target	Inoculation time	Method of injection	
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Attachment 2 : Report for TSE Inactivation Process Validation

(b)(4) Test Data

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Attachment 4 : Test report for the analysis of residual solvent

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Attachment 5 : Risk Analysis

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Attachment 8 : Genotoxicity evaluation report (*In vivo*)

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K113246/S4

K53

PATS corp.
CERTIFICATION BUSINESS

4568 W. 1st Street, Suite 104
Los Angeles, CA 90004USA
e-Mail: gic4usa@yahoo.com
Phone: 213-626-1544 FAX: 213-626-1548

Jan 11 2013
Document Mail Center
Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
SilverSpring. MD20993-0002

FDA CDRH DMC
JAN 14 2013
Received

Refference : K113246
Product: OCS-B
Submitter: **NIBEC CO LTD.**
Applicant: PATS CORP
Manufacturer: **NIBEC CO LTD.**

Dear FDA Officer

According to your requests, we hereby submit the additional information under listed.
Please check the followings.
Thank you.

Table of Contents

-eCopy Statement
-Response to Information Request

Very truly yours,

Daniel

Daniel Nam / General Manager
Authorized Agent for 510K Applicant.

eCopy STATEMENT

I declare that the eCopy I have submitted is exact duplicate of the paper submission for K113246 submitted on January 10th, 2013, created and submitted on a compact disc (CD).

Daniel Nam

General Manager

Date: January 12, 2013

NIBEC
Nanointelligent Biomedical Engineering Corporation

January 7, 2013

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

510K Number: K113246
Response to Information Request
Product: OCS-B™ (bovine derived hydroxyapatite)

To Whom It May Concern:

NIBEC herewith submits in duplicate our response to the deficiencies outlined in Ms. Lauren Giles' email dated December 12, 2012 **(see Tabular – Initial FDA Comments - email dated 12/12/2012)** to 510(k) Number K113246, OCS-B™ (bovine derived hydroxyapatite).

We are confident that the responses provided address the concerns raised in Ms Giles' email support Agency clearance of the above-referenced 510(k) notification for OCS-B™. We would like to thank the Division for its review of our submission.

****

For ease of review of this submission, data displays and discussion have been incorporated into the responses wherever possible. Where additional data or information is required, it is included as an Attachment.

For the convenience of the reviewer, we repeat below in **BOLD AND RED** the deficiencies conveyed by Ms. Lauren Giles, followed by NIBEC's response to each deficiency.

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NIBEC
Nanointelligent Biomedical Engineering Corporation

Sponsor Response

(b)(4)

[redacted]

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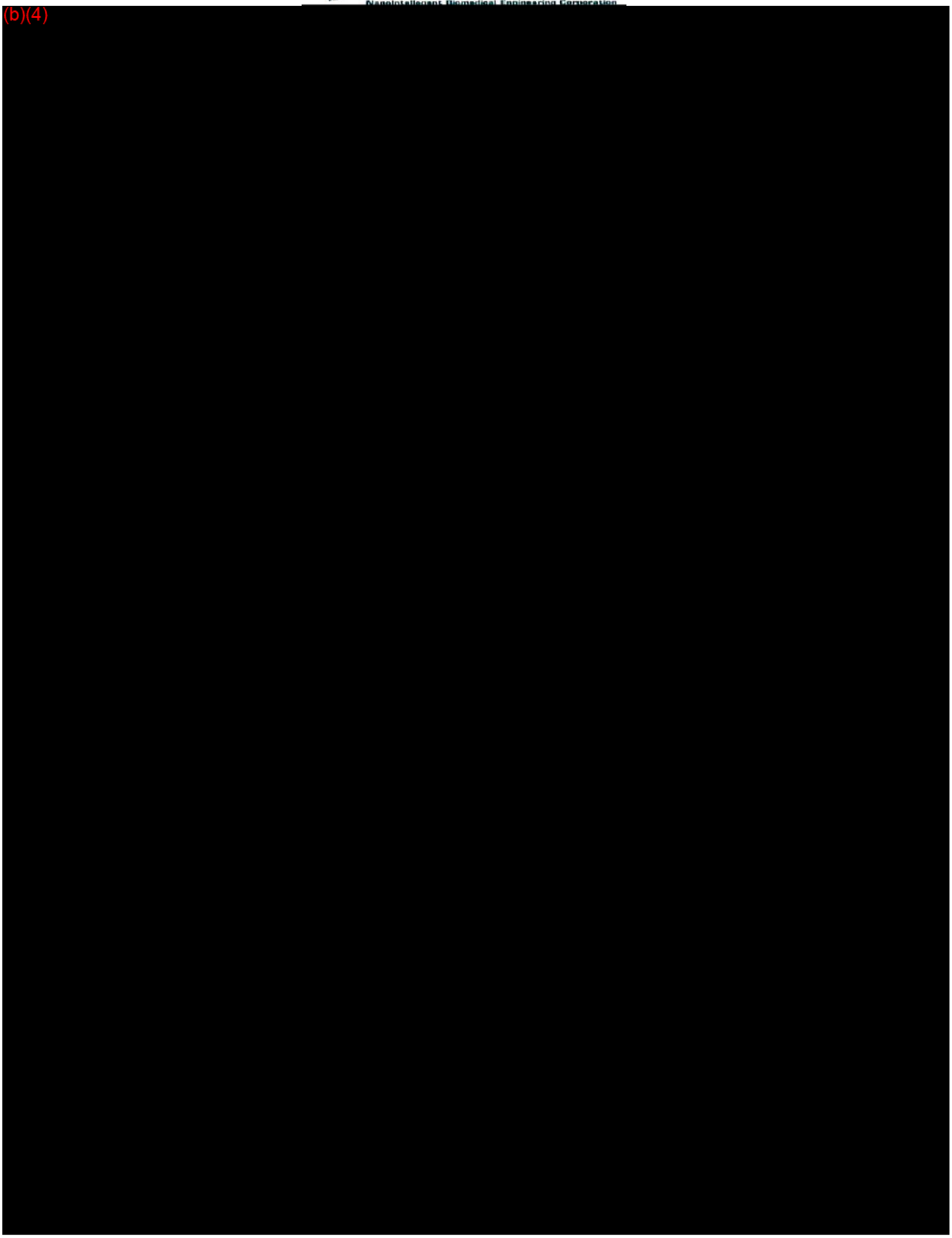

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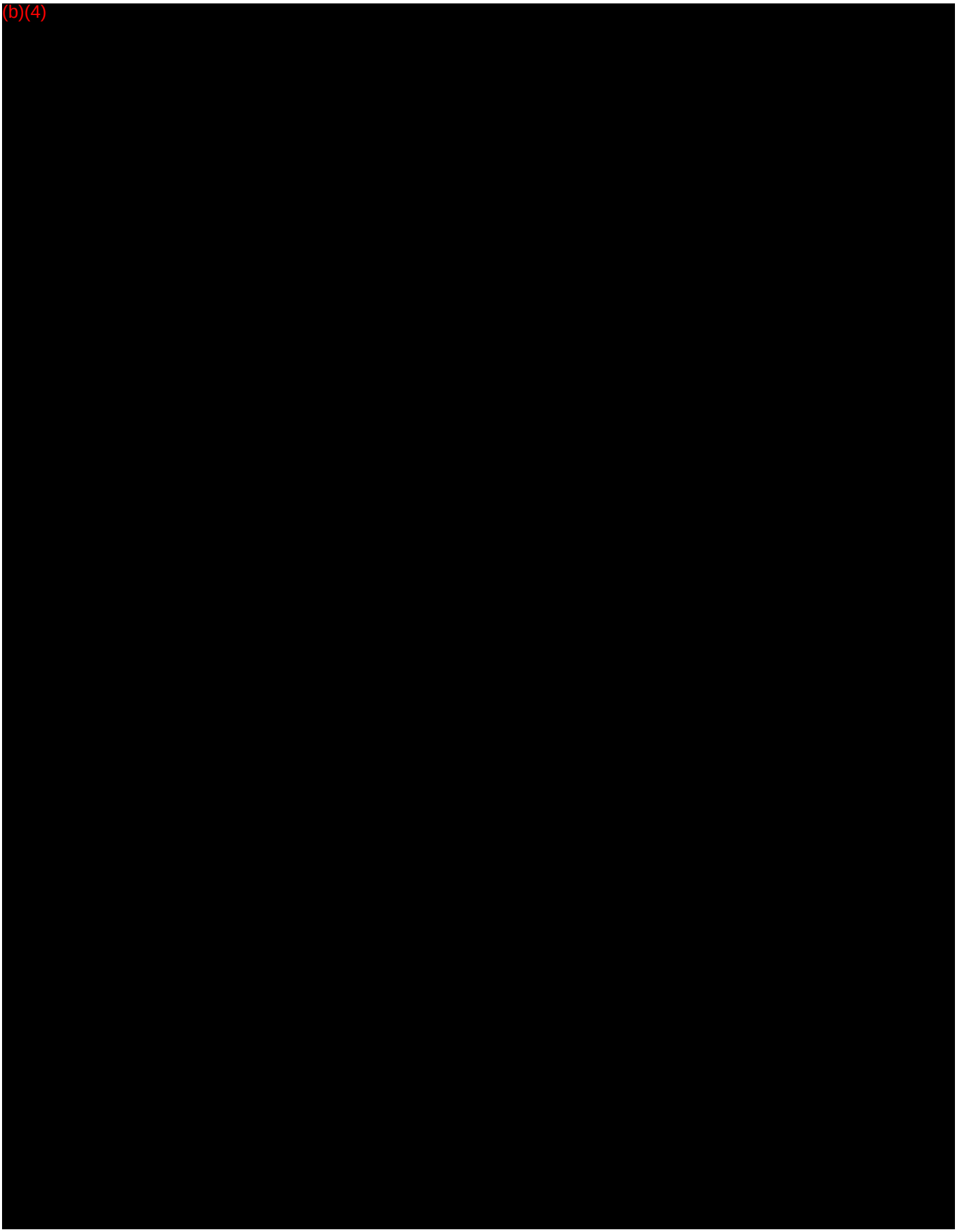

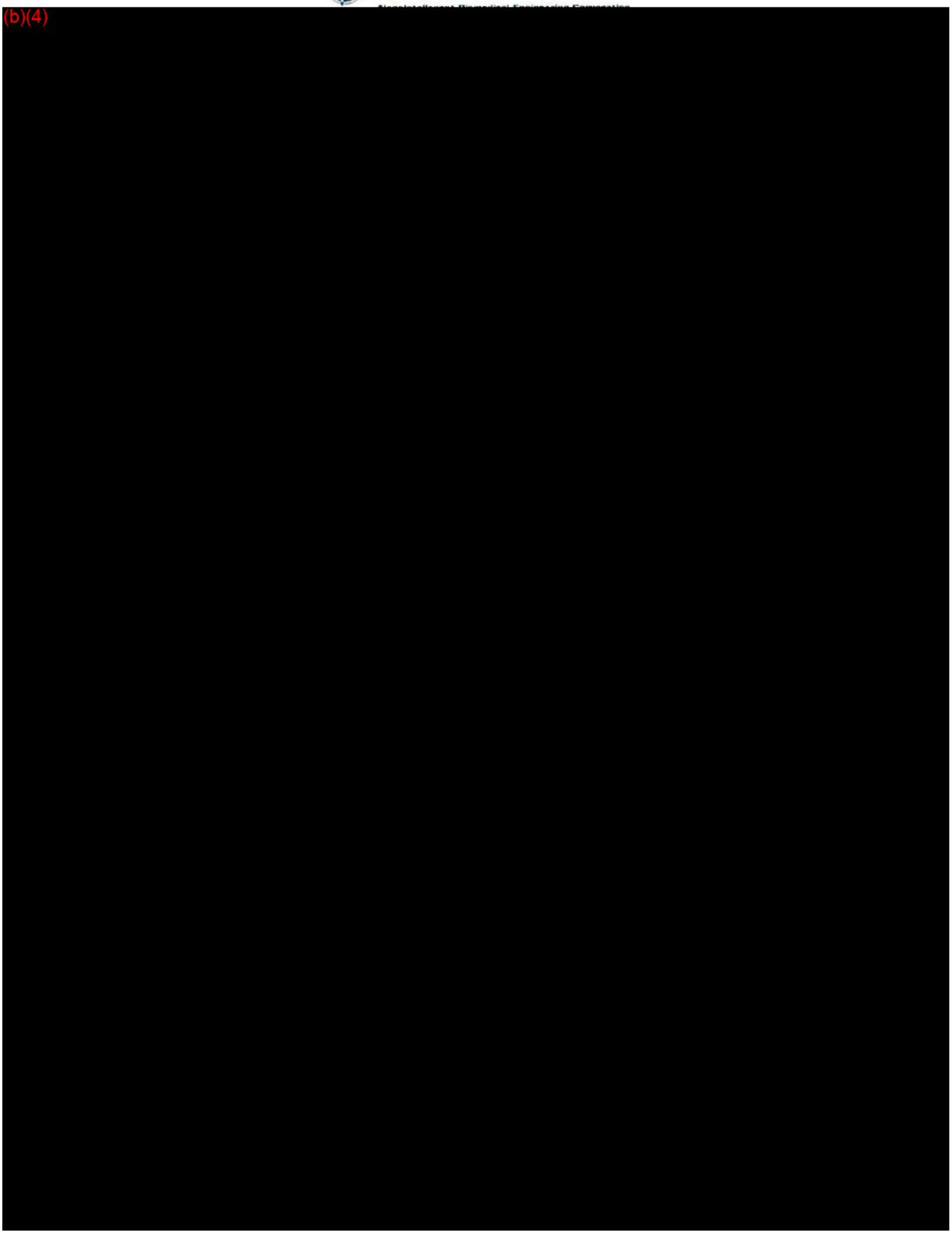

NIBEC

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If you need further information or have other comments, please do not hesitate to contact me. We are looking forward to hearing a favorable response from you. Thank you.

Best wishes,

Yoon Jeong Park, Ph.D.
Manufacturing Quality Manager of NIBEC
E-mail: parkyj@snu.ac.kr
Tel: 82-10-2889-8590

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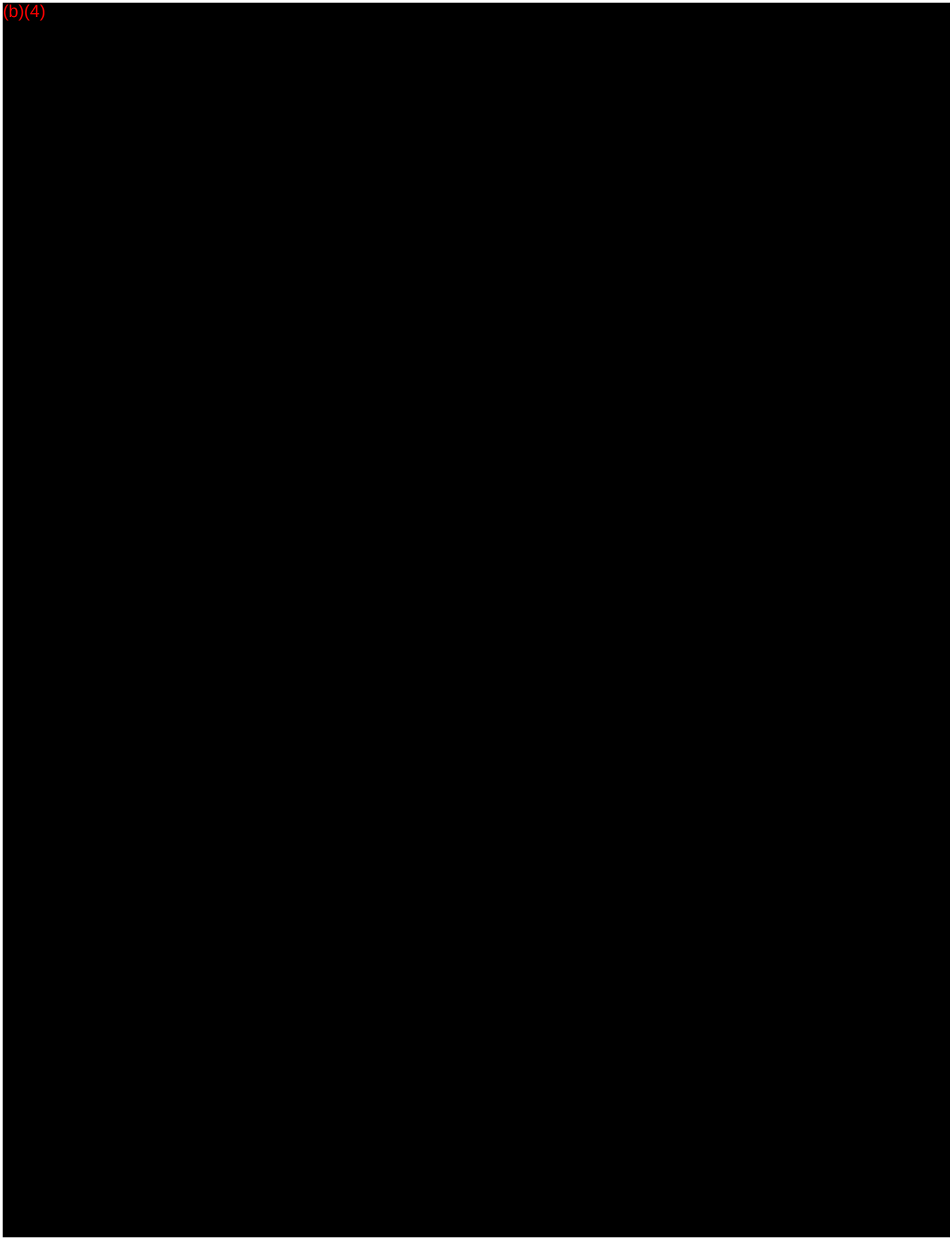

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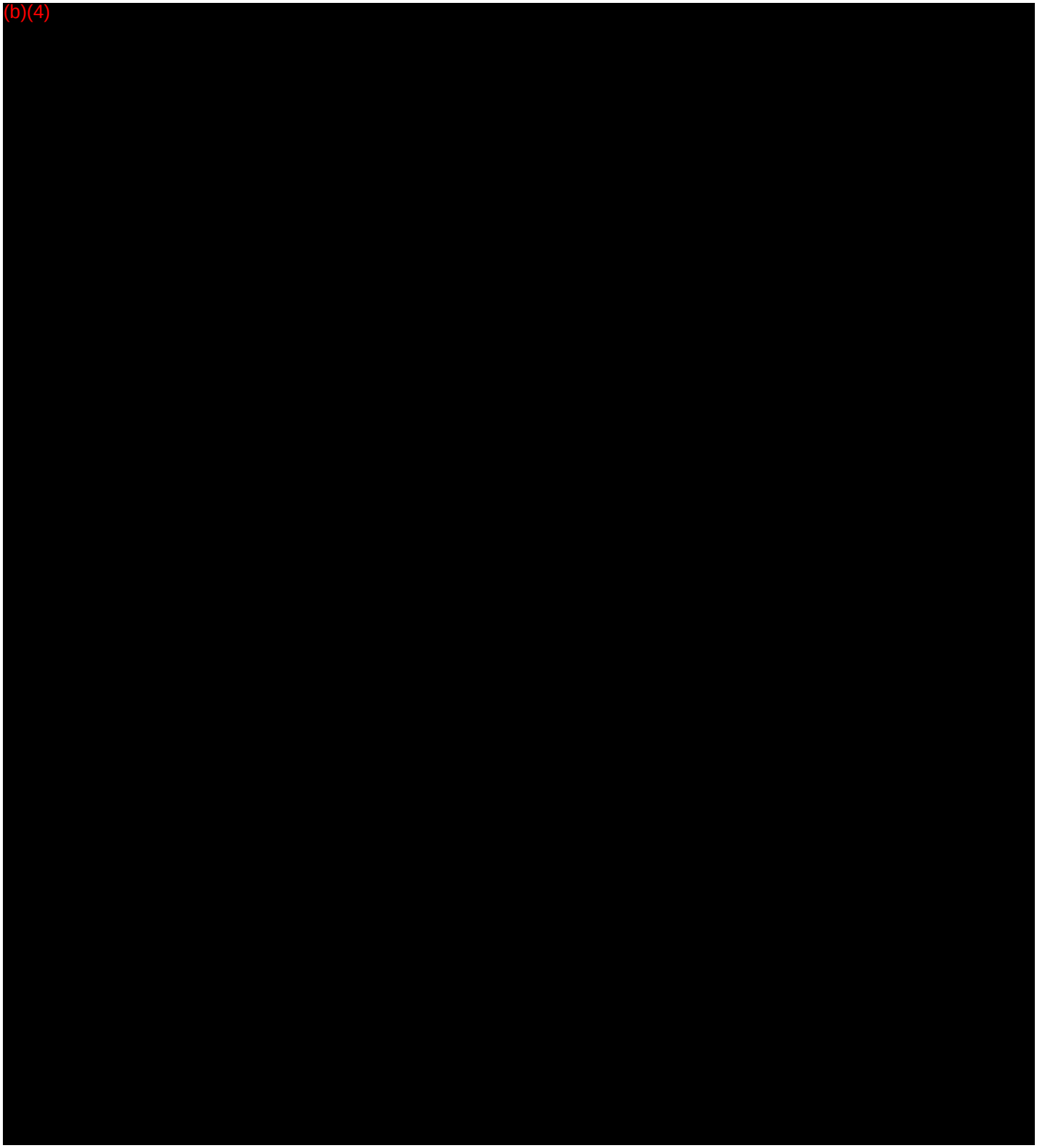

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