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May 15, 2015

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – W066-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Subject: Traditional 510(k) Premarket Notification: Straumann® Variobase® for CEREC®, Abutment Models RN, WN, NC, and RC
User Fee Payment #: (b)(4) [redacted]

Dear Sir or Madam:

Straumann USA, LLC submits this Traditional 510(k) Premarket Notification for the Straumann® Variobase® for CEREC® in accordance with 21 CFR 807.81 on behalf of the device manufacturer, Institut Straumann AG. Two copies of the 510(k) are enclosed: one paper copy and one eCopy in PDF format on CD, which is an exact duplicate of the paper copy. Further, in accordance with the Medical Device User Fee and Modernization Act of 2001 ("MDUFMA"), Straumann USA, LLC has paid the appropriate application fee,

Applicant:
Straumann USA, LLC (on behalf of Institut Straumann AG)
60 Minuteman Road
Andover, MA 01810

Primary Applicant Correspondent:
Sheila Hemeon-Heyer, JD, RAC
Regulatory Consultant
Heyer Regulatory Solutions LLC
(b)(4) [redacted]
Amherst, MA 01002
Telephone: (b)(4) [redacted]
Fax:
(b)(4) [redacted]

Alternate Applicant Correspondent:
Christopher Klaczyk
Director, Regulatory Affairs
Straumann USA, LLC
60 Minuteman Road
Andover, MA 01810
Telephone: (b)(4) [redacted]
Fax: 978-747-0023

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Device Information:

Classification Name:	Abutment, Implant, Dental, Endosseous
Device Product Code:	NHA
Product Classification:	Class II
Panel:	Dental
Regulation Number:	§872.3630
Predicate Device:	K142890 Straumann® Variobase® Abutments

Design and Use of the Device:

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

The Straumann Variobase for CEREC are titanium alloy abutments placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann Variobase for CEREC abutments are indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations.

All digitally designed copings and/or crowns for use with the Straumann Variobase for CEREC abutments are to be designed using Version 3.6 or higher of the Sirona inLab software and a Sirona MC X or MC XL milling unit.

The intended use and fundamental operating principles of the proposed abutments are substantially equivalent to previously cleared Straumann Variobase abutments as

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detailed in this premarket submission. The term "substantially equivalent" as used herein is intended to be a determination of substantial equivalence from an FDA-regulatory point of view under the Federal Food, Drug and Cosmetic Act and relates to the fact that the product can be marketed without premarket approval or reclassification. These products may be considered distinct from a patent point of view. The term "substantially equivalent" is not applicable to, and does not diminish, any patent claim related to this product or the technology used to manufacture the product.

There have been no prior submissions to or discussions with FDA regarding the device described in this 510(k).

Information in this premarket notification is considered proprietary or trade secret or confidential commercial information. The company requests that all such information not be disclosed pursuant to 18 U.S.C. §1905, 5 U.S.C. §552, 21 U.S.C. §331(j), and all other applicable laws and regulations.

We trust that the foregoing information will be sufficient to permit FDA to make a finding of substantial equivalence for the proposed Straumann Variobase for CEREC abutments to the currently marketed devices as presented in this premarket notification.

Please address any questions regarding this 510(k) Premarket Notification to the Primary Applicant Correspondent, (b)(6) [redacted] (b)(4) [redacted] (b)(4) [redacted]

Sincerely,

Adam Daly
Vice President Regulatory Affairs
Straumann USA LLC

Enclosures

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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CONFIDENTIAL

TRADITIONAL 510(K) PREMARKET NOTIFICATION

Straumann® Variobase® for CEREC®

Submitted by: Straumann USA, LLC (on behalf of Institut Straumann AG)
60 Minuteman Road
Andover, MA 01810

Date Submitted: May 15, 2015

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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1 Medical Device User Fee Cover Sheet

Payment Identification Number: (b)(4) [redacted]

The Medical Device User Fee Cover Sheet (Form FDA 3601) begins on the next page.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

(b)(4)

Form FDA 3601 (

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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2 Refuse to Accept Checklist for Traditional 510(k)

The completed Refuse to Accept Checklist for Traditional 510(k) begins on the next page. The applicant understands that the FDA reviewer will conduct an administrative review of this 510(k) within 15 days of the submission log-in date. The completed Refuse to Accept Checklist is provided to assist the reviewer in finding the required 510(k) elements.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Department of Health & Human Services
Food and Drug Administration

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

Contains Nonbinding Recommendations

Print Form

Acceptance Checklist for Traditional 510(k)s

(Should be completed within 15 days of DCC receipt)
The following information is not intended to serve as a comprehensive review.

510(k) #: K Date Received by DCC:

Lead Reviewer:

Branch: Division: Center/Office:

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

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

5) Is there a pending PMA for the same device with the same indications for use? If yes, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.		X
Comments?		
6) If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If yes, consult with the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM - BIMO) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action. Check on web at http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm		
Comments? No clinical studies are submitted for this 510(k)		

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

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.				
- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	**Yes**	**No**	**N/A**	**Comment**
B. Device Description				
10)				
a) If there are requirements regarding the device description, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes device description information to establish that the submitter has followed the device-specific requirement.	X			
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes device description information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.	X			
11) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:				
a) A description of the principle of operation and mechanism of action for achieving the intended effect.	X			
b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	X			
c) A list and description of each device for which clearance is requested.	X			
12) Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions.	X			X
Comments? See Section 11 and Appendix 11-1				
13) If device is intended to be marketed with multiple components, accessories, and/or as part of a system				
a) Submission includes a list of all components and accessories to be marketed with the subject device.	X			
b) Submission includes a description (as detailed in item 11(a) and (b) and 12 above) of each component or accessory.	X			
c) A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance.	X			
C. Substantial Equivalence Discussion				
14) Submitter has identified a predicate device.	X			X
a) Predicate's 510(k) number, trade name, and model number (if applicable) provided. For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding* documenting preamendment status *is available online.*	X			
b) The identified predicate(s) is consistent throughout the submission (i.e., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing.	X			
Comments? See Section 12 and Table 12-1				

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed.				
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.				
- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	**Yes**	**No**	**N/A**	**Comment**
15) Submission includes a comparison of the following for the predicate(s) and subject device				
a) Indications for Use	X			
b) Technology, including features, materials, and principles of operation	X			
16) Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., does not constitute a new intended use; and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate), affect safety or effectiveness, or raise different questions of safety and effectiveness (see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f))	X			X
Comments? See Table 12-1				
D. Proposed Labeling (see also 21 CFR part 801)				
If *in vitro* diagnostic (IVD) device, criteria 17, 18, & 19 may be omitted.				
17) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual) that include a description of the device, its intended use, and the directions for use.	X			X
a) Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided).	X			
b) Submission includes directions for use that - include statements of all conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) AND - includes directions for layperson (see 21 CFR 801.5) OR submission states that device qualifies for exemption per 21 CFR 801 Subpart D	X			
Comments? See Section 13				
18) If indicated for prescription use, labeling includes the prescription use statement (see 21 CFR 801.109(b)(1)) or "Rx only" symbol [See also Alternative to Certain Prescription Device Labeling Requirements]	X			
19) General labeling provisions				
a) Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1).	X			
b) Labeling includes device common or usual name. (21 CFR 801.61)	X			
20)				
a) If there are requirements regarding labeling, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes labeling to establish that the submitter has followed the device-specific requirement.	X			
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes labeling to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.	X			

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed.				
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.				
- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	**Yes**	**No**	**N/A**	**Comment**
c) If there is a special controls document applicable to the device, the submission includes labeling to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.	X			
21) If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10.				
E. Sterilization				
If IVD device and sterilization is not applicable, select "N/A" and criteria below will be omitted from checklist.				
Submission states that the device and/or accessories are: (one of the below must be checked)				
provided sterile				
X provided non-sterile but sterilized by the end user				
non-sterile when used				
Information regarding the sterility status of the device is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
22) Assessment of the need for sterilization information				
a) Identification of device, and/or accessories, and/or components that are provided sterile.				
b) Identification of device, and/or accessories, and/or components that are end user sterilized.	X			
c) Identification of device, and/or accessories, and/or components that are reusable and cleaning /disinfection instructions are provided.				
23) If the device, and/or accessory, and/or a component is provided sterile:			X	
24) If the device, and/or accessory, and/or a component is end user sterilized:				X
a) Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.).	X			
b) A description of method to validate the sterilization parameters (e.g., half-cycle method and full citation of FDA-recognized standard, including date) is provided for each proposed sterilization method. *Note, the sterilization validation report is not required.*	X			
c) Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package, Tyvek packaging, etc.).	X			
d) Submission includes sterilization instructions for end user.	X			
Comments? See Section 14. The sterilization parameters were previously validated for the predicate device. No changes are made that require revalidation. The same sterilization method and parameters are used for the new device.				

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed.				
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.				
- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	**Yes**	**No**	**N/A**	**Comment**
25)				
a) If there are requirements regarding sterility, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes sterility information to establish that the submitter has followed the device-specific requirement.	X			
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes sterility information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	
c) If there is a special controls document applicable to the device, the submission includes sterility information to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.			X	
F. Shelf Life				
26) Proposed shelf life/expiration date stated			X	X
Comments? See section 14. As per the predicate devices, the proposed devices are provided non-sterile and do not have a defined shelf life.				
27) For sterile device, submission includes summary of methods used to establish that device will remain sterile through the proposed shelf life or a rationale for why testing to establish shelf life is not applicable.				
28) Submission includes summary of methods used to establish that device performance is not adversely affected by aging or includes a rationale for why the storage conditions are not expected to affect device safety or effectiveness.				
G. Biocompatibility				
If IVD device, select "N/A" and the below criteria will be omitted from checklist.				
Submission states that there: (one of the below must be checked)				
X are direct or indirect (e.g., through fluid infusion) patient-contacting components.				
are no direct or indirect (e.g., through fluid infusion) patient-contacting components.				
Information regarding the patient contact status of the device is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
29) Submission includes list of patient-contacting device components and associated materials of construction, including identification of color additives, if present	X			
30) Submission identifies contact classification (e.g., surface-contacting, less then 24 hour duration, etc.)	X			

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed.				
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.				
- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	**Yes**	**No**	**N/A**	**Comment**
31) Biocompatibility assessment of patient-contacting components Submission includes: Test protocol (including identification and description of test article), methods, pass/fail criteria, and results provided for each completed test, OR a statement that biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate).		X		X
Comments? See Section 15. The proposed devices are made of the same materials as the predicate devices using the same manufacturing processes. Therefore, the applicant relies on the biocompatibility testing conducted for the predicate device and submitted in K142890 as well as prior 510(k)s for the Straumann Variobase Abutments.				
H. Software				
Submission states that the device: (one of the below must be checked)				
does contain software/firmware.				
X does not contain software/firmware.				
Information regarding whether the device contains software is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
I. EMC and Electrical Safety				
Submission states that the device: (one of the below must be checked)				
does require EMC and Electrical Safety evaluation.				
X does not require EMC and Electrical Safety evaluation.				
Information regarding whether the device requires EMC and Electrical Safety evaluation is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
J. Performance Data - General If IVD device, select "N/A" and the below criteria will be omitted from checklist. Performance data criteria relating to IVD devices will be addressed in Section K.				
36) Full test report is provided for each completed test. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre-defined pass/fail criteria, results summary, conclusions, and an explanation of how the data generated from the test supports a finding of substantial equivalence.	X			X
Comments? See Section 18 and Appendices 18-1 through 18-3 for the performance test reports.				
37)				

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed.				
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.				
- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	**Yes**	**No**	**N/A**	**Comment**
a) If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish that the submitter has followed the device-specific requirement.	X			
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes performance data to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	
c) If there is a special controls document applicable to the device, the submission includes performance data to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.	X			
38) If literature is referenced in the submission, submission includes:			X	
39) For each completed nonclinical (i.e., animal) study conducted			X	
K. Performance Characteristics - In Vitro Diagnostic Devices Only **(Also see 21 CFR 809.10(b)(12))**				
Submission states that the device: (one of the below must be checked)				
is an in vitro diagnostic device.				
is not an in vitro diagnostic device.				
40) Submission includes the following studies, as appropriate for the device type, including associated protocol descriptions, study results and line data:				
a) Precision/reproducibility				
b) Accuracy(includes as appropriate linearity; calibrator or assay traceability; calibrator and/or assay stability protocol and acceptance criteria; assay cut-off; method comparison or comparison to clinical outcome; matrix comparison; and clinical reference range or cutoff.				
c) Sensitivity (detection limits, LoB, LoD, LoQ where relevant for the device type).				
d) Analytical specificity				
41)				
a) If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish that the submitter has followed the device-specific requirement.				
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes performance data to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.				

3 CDRH Premarket Review Submission Cover Sheet

The CDRH Premarket Review Submission Cover Sheet begins on the next page.

Records processed under FOIA Request # 2015-9417; Released by CDRH on 04-25-2016

(b)(4) [redacted]

(b)(4) [redacted]

(b)(4) [redacted]

(b)(4) [redacted]

(b)(4) [redacted]

(b)(4) [redacted]

FORM FL

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9417; Released by CDRH on 04-25-2016

FORM FD

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9417; Released by CDRH on 04-25-2016

FORM FD

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9417; Released by CDRH on 04-25-2016

(b)(4) [redacted]

(b)(6) [redacted] (b)(4) [redacted] (b)(4) [redacted]

[redacted]
FORM FD

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

FORM FD

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4 510(k) Cover Letter

The 510(k) Cover Letter begins on the next page.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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May 15, 2015

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – W066-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Subject: Traditional 510(k) Premarket Notification: Straumann® Variobase® for CEREC®, Abutment Models RN, WN, NC, and RC
User Fee Payment #: (b)(4) [redacted]

Dear Sir or Madam:

Straumann USA, LLC submits this Traditional 510(k) Premarket Notification for the Straumann® Variobase® for CEREC® in accordance with 21 CFR 807.81 on behalf of the device manufacturer, Institut Straumann AG. Two copies of the 510(k) are enclosed: one paper copy and one eCopy in PDF format on CD, which is an exact duplicate of the paper copy. Further, in accordance with the Medical Device User Fee and Modernization Act of 2001 ("MDUFMA"), Straumann USA, LLC has paid the appropriate application fee,

Applicant:
Straumann USA, LLC (on behalf of Institut Straumann AG)
60 Minuteman Road
Andover, MA 01810

Primary Applicant Correspondent:
Sheila Hemeon-Heyer, JD, RAC
Regulatory Consultant
Heyer Regulatory Solutions LLC
(b)(4) [redacted]
Amherst, MA 01002
Telephone: (b)(4) [redacted]
Fax: (b)(4) [redacted]
(b)(4) [redacted]

Alternate Applicant Correspondent:
Christopher Klaczyk
Director, Regulatory Affairs
Straumann USA, LLC
60 Minuteman Road
Andover, MA 01810
Telephone: (b)(4) [redacted]
Fax: 978-747-0023

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9417; Released by CDRH on 04-25-2016

Device Information:

Classification Name:	Abutment, Implant, Dental, Endosseous
Device Product Code:	NHA
Product Classification:	Class II
Panel:	Dental
Regulation Number:	§872.3630
Predicate Device:	K142890 Straumann® Variobase® Abutments

Design and Use of the Device:

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

The Straumann Variobase for CEREC are titanium alloy abutments placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann Variobase for CEREC abutments are indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations.

All digitally designed copings and/or crowns for use with the Straumann Variobase for CEREC abutments are to be designed using Version 3.6 or higher of the Sirona inLab software and a Sirona MC X or MC XL milling unit.

The intended use and fundamental operating principles of the proposed abutments are substantially equivalent to previously cleared Straumann Variobase abutments as

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

detailed in this premarket submission. The term "substantially equivalent" as used herein is intended to be a determination of substantial equivalence from an FDA-regulatory point of view under the Federal Food, Drug and Cosmetic Act and relates to the fact that the product can be marketed without premarket approval or reclassification. These products may be considered distinct from a patent point of view. The term "substantially equivalent" is not applicable to, and does not diminish, any patent claim related to this product or the technology used to manufacture the product.

There have been no prior submissions to or discussions with FDA regarding the device described in this 510(k).

Information in this premarket notification is considered proprietary or trade secret or confidential commercial information. The company requests that all such information not be disclosed pursuant to 18 U.S.C. §1905, 5 U.S.C. §552, 21 U.S.C. §331(j), and all other applicable laws and regulations.

We trust that the foregoing information will be sufficient to permit FDA to make a finding of substantial equivalence for the proposed Straumann Variobase for CEREC abutments to the currently marketed devices as presented in this premarket notification.

Please address any questions regarding this 510(k) Premarket Notification to the Primary Applicant Correspondent, Sheila Hemeon-Heyer, (b)(4) [redacted] (b)(4) [redacted]

Sincerely,

Adam Daly
Vice President Regulatory Affairs
Straumann USA LLC

Enclosures

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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5 Indications for Use Statement

The Indications for Use Statement (FDA Form 3881) begins on the next page.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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FORM

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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6 510(k) Summary

6.1 Submitter's Contact Information

Submitter Name:	Straumann USA, LLC (on behalf of Institut Straumann AG)
Address:	60 Minuteman Road
	Andover, MA 01810
Phone Number:	1-978-747-2575
Fax Number:	1-978-747-0023
Contact Person:	Christopher Klacyzk
Date of Submission:	May 15, 2015

6.2 Name of the Device

Trade Name:	Straumann® Variobase® for CEREC®, Abutment Models RN, WN, RC, NC
Common Name:	Dental Implant Abutment
Classification Name:	Abutment, Implant, Dental, Endosseous
Regulation & Class:	21 CFR §872.3630, Class II
Product Code:	NHA

6.3 Predicate Device

K142890, Straumann® Variobase® Abutments, Models NNC, RN, WN, RC, NC

6.4 Device Description

The Straumann® Variobase® for CEREC® abutments provide the interface for copings or crowns designed and milled using the Sirona CEREC system with four of the Straumann dental implant platforms: RN (Regular Neck), WN (Wide Neck), RC (Regular CrossFit®), and NC (Narrow CrossFit®). The Straumann® Variobase® for CEREC® abutments are pre-manufactured (stock) abutments, sometimes referred to as "Ti-bases," made from a titanium-aluminum-niobium (TAN) alloy. The coronal portion is designed to interface with the pre-machined mounting hole in the milling blanks compatible with the Sirona CEREC MC X and MC XL prosthetic milling systems, and the base portion is available in four models to fit the four Straumann® dental implant platforms listed above. The new components introduced in this 510(k) are shown below.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Straumann® Variobase® for CEREC® Abutments			
RN	WN	RC	NC

Catalog Number	*Description*
022.0019	RN Variobase® for CEREC®
022.0020	WN Variobase® for CEREC®
022.0024	RC Variobase® for CEREC®
022.0025	NC Variobase® for CEREC®
022.0045	RN/WN Basal screw for Variobase®*

*New basal screw for RN and WN abutments (tissue level) to fit the screw hole of the CEREC® material block. The previously cleared (under K062129) basal screws for the RC and NC (bone level) abutments are compatible and will not change.

6.5 Intended Use

The Straumann® Variobase® for CEREC® are titanium alloy abutments placed onto Straumann® dental implants to provide support for customized prosthetic restorations. Straumann® Variobase® for CEREC® are indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations.

All copings and/or crowns for use with the Straumann® Variobase® for CEREC® abutments are to be digitally designed using Version 3.6 or higher of the Sirona inLab software and a Sirona MC X or MC XL milling unit following the instructions for use of those systems.

6.6 Substantial Equivalence and Performance Testing

The Straumann® Variobase® for CEREC® are made of the same TAN alloy material and the same base design as Straumann® Variobase® Abutments previously cleared for the Straumann® implant platforms RN, WN, RC and NC. The only difference is that the coronal portion of these abutments has been designed to interface with the milling

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

blanks used to create copings and crowns with the Sirona CEREC® CAD/CAM system. The new design assures dimensional matching of the CEREC® restorations with the Straumann Variobase for CEREC ®abutments and provides an interlocking feature to augment the cemented adhesion of the restoration onto the abutment. The following performance testing was submitted in this 510(k) to support substantial equivalence:

- Dimensional verification using CEREC® e.max blocks, which confirmed the appropriate fit of the milled coping on the abutment
- Worst case dynamic fatigue testing demonstrating compliance with the minimum required fatigue properties of the Straumann® Variobase® for CEREC® abutments with cemented e.max CADDAM coping
- Process validation of the Straumann® Variobase® for CEREC® within the Sirona CEREC® InLab workflow
- MRI safety testing demonstrating that the Straumann® dental implants are MR conditional

There have been no changes to the materials, packaging, or recommended sterilization method/parameters for these devices as compared to the predicate devices.

6.7 Conclusion

The documentation submitted in this premarket notification demonstrates that the Straumann® Variobase® for CEREC® abutments are substantially equivalent to the predicate Straumann® Variobase® Abutments and do not pose new issues of safety and effectiveness when used as labeled.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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7 Truthful and Accuracy Statement

As Required by 21 CFR 807.87(k)

I certify that, in my capacity as Vice President of Regulatory Affairs at Straumann USA, LLC, 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)

Adam Daly

(Typed Name)

May 14, 2015

(Date)

(Premarket Notification Number)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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8 Class III Summary and Certification

This section is not applicable as the subject devices have been determined to be Class II per 21 CFR 872.3630.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9417; Released by CDRH on 04-25-2016

9 Financial Certification or Disclosure Statement

This section is not applicable as there is no clinical data being submitted to support this premarket notification.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9417; Released by CDRH on 04-25-2016

10 Declarations of Conformity and Summary Reports

The Straumann Variobase for CEREC abutments were designed and tested under the same design controls as for the predicate Straumann Variobase abutments cleared under K142890 and prior 510(k)s and in conformance with the FDA guidance document *"Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments."*

In addition, laboratory tests presented in this 510(k) for the new devices were conducted in accordance with international standards, which are listed in form FDA-3514 CDRH Premarket Submission Review Form and in the table below. Standards Data Report forms FDA-3654 are provided for these standards in **Appendix 10-1**. For the sake of brevity, Straumann is only including Standards Data Report forms for the standards specifically referenced in the present 510(k). As will be discussed in later sections, there have been no changes to the materials used in the subject devices; therefore, no additional biocompatibility or materials characterization testing has been conducted for this 510(k).

Table 10-1. List of Standards Referenced in 510(k)

Standard	Title	FDA Recognition Number
ASTM F2052-14	Standard test method for measurement of magnetically induced displacement forces on medical devices in the magnetic resonance environment	8-381
ASTM F2213-06	Standard test method for measurement of magnetically induced torque on medical devices in the magnetic resonance environment	8-128
ASTM F2182-11a	Standard test method for measurement of radio frequency induced heating on or near passive implants during magnetic resonance imaging	8-227
ASTM F2119-07	Standard test method for evaluation of MR image artifacts from passive implants	8-153
ISO 14801:2007	Dentistry – Implants – Dynamic fatigue test for endosseous dental implants	4-195

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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APPENDIX 10-1: Standard Data Report Forms 3654

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9417; Released by CDRH on 04-25-2016

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]

ASTM F2052-14 Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3] # 8-381		
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: guidance for Industry and FDA Staff: Establishing Safety and Compatibility of Passive Implants in the Ma

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

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[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 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ASTM F2052-14 Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All		☒ 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.

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

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

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

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]

ASTM F2213-06 Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Res

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3] # 8-128		
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: guidance for Industry and FDA Staff: Establishing Safety and Compatibility of Passive Implants in the Ma

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

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[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 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9417; Released by CDRH on 04-25-2016

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ASTM F2213-06 Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Res

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All		☒ 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.

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

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

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
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STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM F2182-11a Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants Durin

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3] # 8-227		
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: guidance for Industry and FDA Staff: Establishing Safety and Compatibility of Passive Implants in the Ma

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

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[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
ASTM F2182-11a Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants Durin

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All		☒ 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

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM F2119-07 Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3] # 8-153		
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]?	☐	☐
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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?	☒	☐

Title of guidance: guidance for Industry and FDA Staff: Establishing Safety and Compatibility of Passive Implants in the Ma

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

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

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CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All		☒ 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.

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TYPE OF 510(K) SUBMISSION

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STANDARD TITLE [1]

ISO 14801:2007 Dentistry - Implants - Dynamic Fatigue Test for Endosseous Dental Implants

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 4-195	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
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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?	☒	☐

Title of guidance: Class II Special Controls Guidance Document: Root-Form Endosseous Dental Implants and Endosseous D

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[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

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CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All		☒ 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?
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TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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11 Device Description

This purpose of this 510(k) premarket notification is to obtain marketing clearance for the Straumann Variobase for CEREC Abutments that can be used to support prosthetic restorations (copings/crowns) designed using the Sirona CEREC InLab (software 3.6 or higher) and milled using the Sirona CEREC MC X and MC XL prosthetic milling systems. The Straumann Variobase for CEREC Abutments are available in four models to fit four Straumann dental implant platforms: RN (Regular Neck), WN (Wide Neck), RC (Regular CrossFit®), and NC (Narrow CrossFit®). These four models are shown below:

Figure 11-1. Straumann® Variobase® for CEREC® Abutments

Tissue Level		Bone Level	
RN	WN	RC	NC

Table 11-1. Catalog Numbers for Devices Included in this 510(k)

Catalog Number	*Description*
022.0019	RN Variobase® for CEREC®
022.0020	WN Variobase® for CEREC®
022.0024	RC Variobase® for CEREC®
022.0025	NC Variobase® for CEREC®
022.0045	RN/WN Basal screw for Variobase®*

*New basal screw for RN and WN abutments (tissue level) to fit the screw hole of the CEREC® material block. The previously cleared (under K062129 and K071357) basal screws for the RC and NC (bone level) abutments are compatible and will not change.

No other new components or accessories are being introduced in this 510(k).

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The CEREC system uses milling blanks with a pre-machined mounting hole. The

(b)(4)

[redacted]

Additional engineering drawings of the devices described in this 510(k) are provided in **Appendix 11-1**.

The Straumann Variobase for CEREC can be used with commercially available milling blanks that include the pre-machined mounting hole compatible with the CEREC MC X and MC XL systems. These are currently available in the following three materials:

(b)(4)

[redacted]

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The design and fabrication of the restorations to be bonded to the Straumann Variobase for CEREC will be completely within the Sirona CEREC workflow in accordance with the Sirona instructions for use. After fabrication, the ceramic restoration is adhesively bonded to the prefabricated Straumann Variobase for CEREC abutment compatible with the Straumann Implant (NC, RC, RN or WN). The dimensions of the Straumann Variobase for CEREC abutments are shown in **Table 11-2** and **Figure 11-3** below.

Table 11-2. Dimensions of the Straumann Variobase for CEREC Abutments

(b)(4)

[redacted]

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Straumann® Variobase™ Abutments with the RN, WN, NC and RC connections for Straumann® dental implants have been previously cleared in the 510(k)s shown below in **Table 11-3**.

Table 11-3 – Straumann dental implant platforms with corresponding clearances

(b)(4)

[redacted]

Use of Straumann Variobase for CEREC Abutments in the Sirona Workflow

Detailed instruction for use of the Straumann Variobase for CEREC Abutments in the Sirona workflow are provided in the device instructions for use, which can be found in **Section 13.2** of this 510(k). These instructions are summarized below.

The restoration is designed by following the instructions for the Sirona CADCAM system. The restoration must be designed and fabricated using Version 3.6 or higher of the inLab software and an MC X or MC XL milling unit. The Straumann Variobase for CEREC is

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compatible with the accessory components used in the Sirona CEREC or inLab system (e.g., scanbodies, mill cutters) and with material milling blocks having a pre-machined screw hole (b)(4) [redacted] (b)(4)

The abutment is fixed either intraorally to the implant or extraorally to the implant analog on the master cast by tightening the basal screw hand-tight. The scan-body is inserted to the Straumann Variobase for CEREC, and the scanning is completed to create a digital working model (either intraoral scan or scan of the master cast). A(b)(4) [redacted] (b)(4) The prosthetic restoration is processed and finalized prior to bonding to the Straumann Variobase for CEREC according to the material manufacturer's instructions for use.

Prior to bonding a fit test should be performed either on a model or intraorally. (b)(4) [redacted] elf-adhesive dental cement is applied on the abutment following the instructions for use of both the dental material and bonding material manufacturer. The prosthetic restoration is bonded to the abutment, and excess cement is immediately removed.

Prior to insertion, the restoration is removed from the master cast or the implant analog and is cleaned, disinfected and sterilized per the Straumann Variobase for CEREC instructions for use. The healing cap, closure screw or temporary restoration is removed, and the interior of the implant and the abutment are thoroughly cleaned and dried.

For screw-retained prosthetic solutions:

The sterilized restoration is carefully placed into the patient's mouth using tweezers. The retentive elements of the implant-abutment connection must be properly aligned. The abutment is screwed into the dental implant using the appropriate basal screw and a Straumann SCS Screwdriver. (b)(4) [redacted] he screw channels are closed with cotton and a sealing compound (e.g. gutta-percha or composite restorative material), which allows later removal of the Straumann Variobase for CEREC prosthetic components in case a crown replacement is necessary.

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Optional for cement-retained restorations:

Self-adhesive dental cement is applied on the Straumann Variobase prosthetic components. Only suitable self-adhesive cementation systems for the material shall be used. The prosthetic restoration is bonded to the Straumann Variobase prosthetic components following both the prosthetic material and bonding material manufacturer. Excess cement should be immediately removed from the Straumann Variobase prosthetic components and the lower margin of the prosthetic restoration is polished after the cement has set.

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APPENDIX 11-1: Engineering Drawings

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Schematic Drawings

(b)(4) Schematic Drawings

(b)(4) Schematic Drawings

(b)(4) Schematic Drawings

(b)(4) Schematic Drawings

(b)(4) Schematic Drawings

(b)(4) Schematic Drawings

(b)(4) Schematic Drawings

(b)(4) Schematic Drawings

12 Substantial Equivalence Discussion

Within the meaning of the Medical Device Amendments Act of 1976, the proposed Straumann Variobase for CEREC Abutments in this 510(k) premarket notification are substantially equivalent to the Straumann Variobase Abutments previously cleared for marketing under K142890, which had previously been found substantially equivalent to Straumann Variobase Abutments cleared under K132219 and K120822. For the sake of brevity, this 510(k) will only include a substantial equivalence discussion to the most recently cleared predicate deices under K142890.

Please see **Appendix 12-1** for the 510(k) Summary for the Straumann Variobase Abutments cleared under K142890.

The following discussion addresses the questions in the FDA 510(k) Substantial Equivalence Decision Making Process, including a discussion of the similarities and differences between the proposed and predicate Straumann Variobase Abutments. Please also see **Table 12-1** for comparison of technical characteristics between the proposed and predicate devices.

Does the new device have the same intended use(s) as the predicate device(s)?

Yes, except for minor wording differences, the new and predicate devices have the same intended use to be placed into Straumann dental implants and to provide support for prosthetic reconstructions.

Does the new device have the same indications for use as the predicate device(s)?

Yes, the new and predicate devices are all pre-manufactured (stock) Ti-base abutments indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations and intended for use with Straumann dental implants. The only difference in the indications for use is that the proposed Variobase for CEREC abutments are specifically indicated for use with restorations fabricated using the Sirona CEREC MC X and MC XL milling systems.

Do the differences alter the intended therapeutic/diagnostic/etc. effect?

No. The different systems used to produce the prosthetic restoration (which are not part of this 510(k)) do not alter the intended use of the proposed devices, which is to act as the interface between the prosthetic restoration and the endosseous implant.

Does the new device have the same technological characteristics, e.g., design, materials, etc.?

The technological characteristics of the Variobase for CEREC abutments are very similar to the predicate Variobase abutments, including the same material (TAN) and same base design to interface with Straumann dental implants RN, WN, NC and RC. Note that base NNC (Narrow Neck CrossFit®) is not offered for Variobase for CEREC because the Sirona system does not support the NNC configuration.

(b)(4) [redacted]

Could the new characteristics affect safety or effectiveness?

Yes, the new design of the coronal aspect of the Variobase for CEREC abutments could affect safety and effectiveness. However, testing provided in **Section 18** of this 510(k) confirms that prosthetic restorations designed and fabricated using the Sirona CEREC systems are compatible with the Straumann Variobase for CEREC abutments as demonstrated by (b)(4) [redacted], dimensional, and dynamic fatigue validations.

Do the new characteristics raise new types of safety or effectiveness questions?

No, the types of safety and effectiveness questions for the proposed and predicate devices are the same. These include questions concerning the following:

- Biocompatibility of the materials (same materials)
- Appropriate design for interfacing with the restoration (b)(4) [redacted] testing
- Appropriate design for interfacing with the endosseous implant (same base designs for RN, WN, NC, and RC)
- Sterilization validation (same method and parameters)

Are the descriptive characteristics precise enough to ensure equivalence or are performance data available to assess equivalence?

Yes, information and test data to address all of the above questions are provided in this 510(k).

Do the results of the performance testing demonstrate equivalence?

Yes, the results of the performance testing demonstrate that the Straumann Variobase for CEREC abutments are substantially equivalent to the Straumann Variobase Abutments cleared under prior 510(k)s, the most recent being K042890.

Table 12-1 below provides a comparison matrix of the proposed and predicate devices.

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Table 12-1. Technical Comparison of the Proposed and Predicate Devices

FEATURE	PROPOSED DEVICE Straumann® Variobase™ for CEREC Abutments	PRIMARY PREDICATE DEVICE Straumann® Variobase™ Abutments K142890	EQUIVALENCE DISCUSSION
Intended Use	Intended to be placed into Straumann dental implants to provide support for prosthetic reconstructions such as crowns.	Prosthetic components directly connected to the endosseous dental implant are intended for use as an aid in prosthetic rehabilitations.	Substantially equivalent
Indications for Use	The Straumann Variobase for CEREC are titanium alloy abutments placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann Variobase for CEREC abutments are indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations. All digitally designed copings and/or crowns for use with the Straumann Variobase for CEREC abutments are to be designed using Version 3.6 or higher of the Sirona inLab software and a Sirona MC X or MC XL milling unit.	The Straumann® Variobase™ Abutment is a titanium base placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann® Variobase™ Abutments are indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations. All digitally designed copings and/or crowns for use with the Straumann® Variobase™ Abutment system are intended to be sent to Straumann for manufacture at a validated milling center.	Different workflows used to design and fabricate the restorations. Coronal aspect of proposed device is designed to interface with copings/crowns fabricated from milling blanks containing pre-machined holes for use with the CEREC CADCAM system. Substantial equivalence based on design validation testing.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

FEATURE	PROPOSED DEVICE Straumann® Variobase™ for CEREC Abutments	PRIMARY PREDICATE DEVICE Straumann® Variobase™ Abutments K142890	EQUIVALENCE DISCUSSION
Contraindications	Patients with known allergies or hypersensitivity to chemical ingredients of the following materials used: titanium (Ti), titanium alloy Ti6Al7Nb (titanium-aluminum-niobium or TAN)	Allergies or hypersensitivity to materials used: Titanium alloy Ti-6Al-7Nb (titanium-aluminum-niobium or TAN).	Same
Ti-base Material	Titanium-Aluminum-Niobium alloy (Ti-6Al-7Nb)	Titanium-Aluminum-Niobium alloy (Ti-6Al-7Nb)	Same
Abutment Diameter (base)	4.5 mm – 7.0 mm	3.8 mm – 7.0 mm	Substantially equivalent Proposed device models do not include NNC (3.8 mm dia)
Abutment Height	4.7 mm	3.5 – 4.5 mm	Substantially equivalent
Coping/ Crown Material	Compatible with any milling blanks cleared for use with the CEREC MC X and MC XL milling systems (i.e., containing the pre-machined mounting hole). Currently available: inCoris ZI meso (K123664) Ivoclar IPS e.max CAD (K132209) Ivoclar Telio CAD (K093708)	Traditional Workflow: Type 4 Metals (ISO 22674) IPS e.max® Press Ceramic Digital Workflow: polycon® ae (temporary) zerion® (permanent) IPS e.max® CAD Ceramic (permanent) coron® (permanent)	Substantially equivalent All materials to be used for coping/crown have previously been cleared and are not the subject of this 510(k).
Design Workflow	Per the Sirona CEREC InLab, software version 3.6 or later	Wax-up or Open CAD	Substantially equivalent
Manufacturing Workflow	Per the Sirona Cerec MC X and MC XL milling systems	Traditional casting or pressing or Straumann Milling	Substantially equivalent

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9417; Released by CDRH on 04-25-2016

FEATURE	PROPOSED DEVICE Straumann® Variobase™ for CEREC Abutments	PRIMARY PREDICATE DEVICE Straumann® Variobase™ Abutments K142890	EQUIVALENCE DISCUSSION
Mode of Action	Screw-retained or cement retained	Screw-retained or cement retained	Same
Reusable	No	No	Same

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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APPENDIX 12-1: 510(k) Summary for Predicate Device, K142890

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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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 9,2015

Straumann USA, LLC
Jennifer M. Jackson M.S.
Senior Regulatory Affairs Project Manager
60 Minuteman Road
Andover, MA 01810

Re: K142890
Trade/Device Name: Straumann Variobase Abutment NNC, Straumann Variobase Abutment RN, Straumann Variobase Abutment WN, Straumann Variobase Abutment NC, Straumann Variobase Abutment RC, IPS e.max CAD MO Coping, IPS e.max CAD LT Crown, IPS e.max CAD HT Crown, coron CoCr Single Unit
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: December 22, 2014
Received: December 23, 2014

Dear Ms. Jackson,

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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K142890

Device Name
Straumann® Variobase™ Abutment NNC, Straumann® Variobase™ Abutment RN, Straumann® Variobase™ Abutment WN, Straumann® Variobase™ Abutment NC, Straumann® Variobase™ Abutment RC, IPS e.max® CAD MO Coping, IPS e.max® CAD LT Crown, IPS e.max® CAD HT Crown, coron CoCr Single Unit

Indications for Use *(Describe)*
The Straumann® Variobase™ Abutment is a titanium base placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann® Variobase™ Abutments are indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations. All digitally designed copings and/or crowns for use with the Straumann® Variobase™ Abutment system are intended to be sent to Straumann for manufacture at a validated milling center.

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

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

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

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

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

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

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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5 510(k) Summary

5.1 Submitter's Contact Information

Straumann USA, LLC (on behalf of Institut Straumann AG)

60 Minuteman Road

Andover, MA 01810

Phone Number: 1-978-747-2509

Fax Number: 1-978-747-0023

Contact Person: Jennifer M. Jackson, MS

Date of Submission: January 8, 2015

5.2 Name of the Device

Trade Name: Straumann® Variobase™ Abutment NNC, Straumann® Variobase™ Abutment RN, Straumann® Variobase™ Abutment WN, Straumann® Variobase™ Abutment NC, Straumann® Variobase™ Abutment RC, IPS e.max® CAD MO Coping, IPS e.max® CAD LT Crown, IPS e.max® CAD HT Crown, coron CoCr Single Unit

Common Name: Dental Implant Abutment

Classification Name: Abutment, Implant, Dental, Endosseous

Regulation Number: §872.3630

5.3 Predicate Device(s)

- K120822, Straumann CARES Variobase Abutment NNC, RN, WN, NC, RC (Institut Straumann AG)
- K120053, IPS e.max® Press – Abutment Solutions (Ivoclar Vivadent AG)
- K132209, IPS e.max® CAD Abutment Solutions (Ivoclar Vivadent AG)
- K132219, Straumann Variobase Abutments

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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5.4 Device Description

The Straumann® Variobase™ Abutments are pre-manufactured (stock) abutments, sometimes referred to as "Ti-bases". Straumann® Variobase™ Abutments are available to fit Straumann® dental implant platforms NNC (Narrow Neck CrossFit®), RN (Regular Neck), WN (Wide Neck), NC (Narrow CrossFit®), and RC (Regular CrossFit®). A dental laboratory technician would design the corresponding coping and/or crown (the second component of the Variobase two-piece abutment) and/or prosthetic restoration in the dental laboratory via their preferred workflow for pressing, casting, or milling using either a burnout coping or STL model for open CAD software. The coping and/or crown would be manufactured via traditional laboratory methods for pressing or casting, or via validated Straumann milling.

The purpose of this submission is to add coping and/or crown materials to the Straumann® Variobase™ Abutment portfolio for the previously cleared validated Straumann milling workflow and to expand the design/manufacturing workflow to include in-lab pressing and casting techniques and materials.

5.5 Intended Use

The Straumann® Variobase™ Abutment is a titanium base placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann® Variobase™ Abutments are indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations.

5.6 Indications for Use

The Straumann® Variobase™ Abutment is a titanium base placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann® Variobase™ Abutments are indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations. All digitally designed copings and/or crowns for use with the Straumann® Variobase™ Abutment system are intended to be sent to Straumann for manufacture at a validated milling center.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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5.7 Technological Characteristics

Straumann® Variobase™ Abutments are two-piece abutments consisting of a pre-manufactured (stock) abutment made from a titanium-aluminum-niobium alloy and a coping and/or crown which is designed in the dental laboratory by a dental technician and manufactured via traditional in-lab methods of pressing or casting, or via validated Straumann milling.

The Ti-base components of the Straumann® Variobase™ Abutments are identical to the Ti-base components of the Straumann predicates (K120822 and K132219). The CAD and press materials which may be used to manufacture the coping/crown component of the Straumann Variobase Abutments are identical to the identified predicate devices and include:

Casting:	Type 4 metals (ISO 22674)
	Base metal alloy (e.g., cobalt-chromium (CoCr))
	Noble metal alloy (e.g., gold alloy)
Pressing:	IPS e.max® Press Ceramic (K120053)
CAD:	IPS e.max® CAD Ceramic (K132209)
	coron®

5.8 Performance Testing

The material used in the manufacture of Straumann® Variobase™ Abutments is a titanium-aluminum-niobium alloy which meets the requirements of ISO 5832-11. Bench testing was performed with each coping/crown material to evaluate the performance of the proposed Straumann® Variobase™ Abutments. Dynamic fatigue tests were conducted in according to the FDA guidance document *"Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments"*.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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5.9 Conclusion

The documentation submitted in this premarket notification demonstrates that the Straumann® Variobase™ Abutments are substantially equivalent to the predicate devices and do not pose new issues of safety and effectiveness when used as labeled.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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13 Proposed Labeling

13.1 Package Label

The package labels for the Straumann Variobase for CEREC follow the same format as the package labels for the predicate Straumann Variobase Abutments. An example of the proposed package label is shown below for the RN model. Package labels for all models will be the same except for the model designation (RN, WN, NC or RC).

(b)(4) Draft Document

[redacted]

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An additional label shown below will be affixed to the outside of the device packaging for the subject devices sold in the US to comply with the FDA requirement of English translation of symbols in accordance with 21 CFR 801.15(c)(1).

Explanation of Symbols	
	Consult operating instructions
	Caution, consult accompanying documents
	Do not re-use

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

13.2 Instructions for Use

The following is a draft of the instructions for use of the Straumann Variobase for CEREC.

7011719/A/00 03/15

Instructions for use: Straumann® Variobase® for CEREC®

Institut Straumann AG, Peter-Merian-Weg 12, CH-4002 Basel/Switzerland,
www.straumann.com

English

CAUTION: Federal law restricts this device to sale by or on the order of a dental professional.

Straumann® Variobase® for CEREC® Abutments			
NC	RC	RN	WN

1. Product description

Abutments

Abutments are placed into dental implants to provide support for prosthetic reconstructions such as crowns and bridges.

Basal screws

Basal screws are used for the fixation of the abutment to the dental implant.

2. Intended use

Straumann® Variobase® for CEREC® Abutments are intended to be placed into Straumann dental implants to provide support for prosthetic reconstructions such as crowns.

3. Indications

The Straumann® Variobase® for CEREC® are titanium alloy abutments placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann® Variobase® for CEREC® abutments are indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations.

All digitally designed copings and/or crowns for use with the Straumann® Variobase® for CEREC® abutments are to be designed using Version 3.6 or higher of the Sirona inLab software and a Sirona MC X or MC XL milling unit.

4. Contraindications

Contraindicated in cases with known allergies or hypersensitivity to chemical ingredients of the following materials: titanium (Ti), titanium alloy (Ti6Al7Nb (titanium-aluminum-niobium or TAN)).

5. Side effects, interactions and precautions; complications with Straumann implants

Information related to side effects, interactions and precautions; complications with Straumann implants should be provided to the patient.

6. Warnings

- Dental cement or any other material used for the attachment of prosthetic components should be processed as specified by the manufacturer. An implant is only to be restored with the corresponding original abutment compatible with that specific implant.
- The WN Variobase® for CEREC® is not compatible with the Sirona Gallileos Software. The use of the WN Variobase® for CEREC® in the guided surgery workflow may lead to a restoration which does not fit occlusally.

7. Caution/Precautions

- Straumann prosthetic devices must be secured to prevent aspiration during intraoral use.

- Failure to follow the procedures outlined in these instructions may lead to any or all of the following complications:
  - Aspiration or swallowing of components
  - Infection
  - Damage to the implant, abutment, components or tooling
  - Loosening of the abutment or other components
  - Improper final restoration or malfunction of the crown, bridge or other final prosthetics
  - Impairment of the patient's chewing function
  - Failure of the implant
  - Removal of the implant
- The Straumann® Variobase® for CEREC® is a single-use device.
- Always place temporary restorations out of occlusion. Use temporary cement for the attachment of temporary prosthetic restorations. Dental cement or any other material used for the attachment of prosthetic components should be processed as specified by the manufacturer.
- Place implant-borne restorations only in occlusion when the implant is completely osseointegrated.
- Non-clinical testing has demonstrated that metallic components of the Straumann® Dental Implant System, including the Straumann® Variobase® for CEREC®, are **MR Conditional**. A patient with any of the metallic devices in the Straumann® System can be safely scanned in an MR system meeting the following conditions:
  - Static magnetic field of 3.0 T.
  - Maximum spatial field gradient of 3000 gauss/cm (0.3 T/m).
  - Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode).
  - Under the scan conditions defined above, the worst case Straumann device construct exhibited displacement forces of less than 0.1 N (less than the force of gravity).
  - Under the scan conditions defined above, the metallic components of the Straumann® Dental Implant System are expected to produce a maximum

temperature rise of less than 5.9□C after 15 minutes of continuous scanning.

- Under 1.5T scan conditions, the metallic components of the Straumann® Dental Implant System are expected to produce a maximum temperature rise of less than 5.2□C after 15 minutes of continuous scanning.
- In non-clinical testing, the image artifact caused by the device extends approximately 26 mm from the metallic components of the Straumann® Dental Implant System when imaged with a gradient echo pulse sequence in a 3.0T MRI system.
- In non-clinical testing, the image artifact caused by the device extends approximately 13 mm from the metallic components of the Straumann® Dental Implant System when imaged with a spin echo pulse sequence in a 3.0T MRI system.

8. Compatibility information

Straumann implants and the prosthetic components are available in a variety of configurations to meet your clinical needs. The label on each product uses abbreviations to help you identify whether a particular abutment or coping is compatible with the implant that you are restoring. The implant as well as the prosthetic component contains an identifier for the connection type, summarized in the table below.

Implant connection type	Compatible parts
NC (Narrow CrossFit®)	parts labeled NC
RC (Regular CrossFit®)	parts labeled RC
RN (Regular Neck)	parts labeled RN
WN (Wide Neck)	parts labeled WN

9. Cleaning and disinfection

Straumann® Variobase® for CEREC® abutments and components are non-sterile when delivered. Before placing the restoration in the patient's mouth, the product must be cleaned, disinfected and sterilized. Straumann recommends the following procedure for cleaning, disinfection and sterilization of abutments prior to use:

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1. Clean the abutment rinsing it under running water while brushing the outer and inner side with adequate brushes.
2. The pre-treated product is to be cleaned/disinfected in an automated washer disinfector. Select the appropriate program according the manufacturer's instructions.

Consult the brochure *Guideline for Cleaning, Disinfection and Sterilization for Straumann® Implant-borne Prosthetic Components*, 152.802 for detailed information.

10. Sterilization

The restoration may be sterilized unwrapped or can be placed in an accessory cassette and packaged twice in common sterilization wraps (paper/film/bags). Steam sterilize according to the following parameters.

Material	Method	Conditions
Variobase® for CEREC®, TAN Screw, TAN	Autoclave (moist heat) Displacement: gravity or fractionated vacuum	134 °C (237 °F) 5 min

Please note: User should ensure the use of the appropriate biological indicator for the sterilizer and parameters used.

Please note: The user should consult the coping/restoration material manufacturer's recommendations regarding sterilization.

Caution: Use devices immediately after sterilization. Do not store sterilized devices.

Consult the brochure *Guideline for Cleaning, Disinfection and Sterilization for Straumann® Implant-borne Prosthetic Components*, 152.802 for detailed information.

11. Procedure

Please note: In order to provide a dimensionally accurate original Straumann WN implant-abutment connection, the WN Variobase® for CEREC® is not compatible with the Sirona Gallileos Software. The use of the WN Variobase® for CEREC® in the guided surgery workflow may lead to a restoration which does not fit occlusally.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Use and compatibility of the Straumann® Variobase® for CEREC®:

- The Straumann® Variobase® for CEREC® can be used for screw- and cement-retained restorations.
- When using a digital workflow the standard procedure according to the system provider instructions apply.
- Select a comparable third party Ti-base from the implant library of the CADCAM system to design the restoration.
- The Straumann® Variobase® for CEREC® requires Version 3.6 or higher of the inLab software and use of a MC X or MC XL milling unit.
- The Straumann® Variobase® for CEREC® is compatible with the accessory components used in the Sirona CEREC® or inLab system (e.g., scanbodies, mill cutters).
- The abutment coronal design is compatible with material milling blocks having a pre-machined screw hole (e.g., IPS e.max CAD, inCoris ZI meso).

a.) Fabricate the prosthetic restoration

Please note: The instructions for use of the material manufacturer shall be followed.

Please note: The diameter or height of the Straumann® Variobase® for CEREC® abutments must not be reduced, e.g. by grinding.

1) Fix the abutment either intraorally to the implant or extraorally to the implant analog on the master cast by tightening the basal screw hand-tight.
2) Insert the scan-body to the Straumann® Variobase® for CEREC®.
3) Proceed with an intraoral scan or scan the master cast to create a digital working model.
4) Select a comparable third party Ti-base from the implant library of the CADCAM system to design the restoration.
5) Process and finalize the prosthetic restoration according to the material manufacturer's instructions for use. Always finalize the crown or coping prior to bonding to the Straumann® Variobase® for CEREC®.

b.) Bonding the prosthetic restoration onto the abutment

Please note: Only the surfaces of the Straumann® Variobase® for CEREC® intended for gluing with a mesostructure or anatomic reduced crown must be sandblasted (50 µm aluminium oxide, max. 2 bar).

Please note: Prior to bonding a fit test should be performed either on a model or intraorally.

1) Clean the abutment with alcohol or steam.
2) Fix the abutment to the implant analog or polishing tool by tightening the basal screw hand-tight.
3) Seal the screw channel with wax.
4) Apply self-adhesive dental cement on the Straumann® Variobase® prosthetic components. Only suitable self-adhesive cementation systems for the material shall be used. Follow the instructions for use of both the dental material and bonding material manufacturer. (Straumann recommends Panavia™ F2.0 by Kuraray).
5) Bond the prosthetic restoration to the Straumann® Variobase® prosthetic components.
6) Immediately remove excess cement from the Straumann® Variobase® prosthetic components.
7) Optional for cement-retained restorations: Make a crown following the standard procedure according to the material manufacturer's instructions and finalize it.
8) Clean the restoration prior to further processing.

c.) Insertion

1) Remove the restoration form the master cast or the implant analog.
2) Clean, disinfect and sterilize the device as described in sections 10 and 11 of these instructions for use.
3) Remove the healing cap, closure screw or temporary restoration.
4) Clean and dry the interior of the implant and the abutment thoroughly.

   For screw-retained prosthetic solutions:

5) Place the sterilized restoration into the patient's mouth. All components should be placed carefully using tweezers. Straumann® Variobase® prosthetic components are inserted using a Straumann® SCS Screwdriver.
6) Make sure that the retentive elements of the implant-abutment connection are properly aligned.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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7) Use the screw delivered with the abutment to screw the abutment into the dental implant.

   Please note: Always ensure that the surfaces of threads and screw heads are clean and that a new screw is used for the restoration.

8) Tighten the screws with the respective driver along with the Ratchet (046.119) and the Torque Control Device (046.049). The respective torque is described in the table below:

Device type	Tightening torque	Special considerations
Abutments (permanent)	35 Ncm	n/a
Temporary abutments	15 – 35 Ncm	Tighten only to 35 Ncm if the implant is fully osseointegrated
Components on implant analog	Hand-tight	n/a

9) Close the screw channels with cotton and a sealing compound (e.g. gutta-percha or composite restorative material). This allows a later removal of the Straumann® Variobase® prosthetic components in case a crown replacement is necessary.

   Optional for cement-retained restorations:

10) Apply self-adhesive dental cement on the Straumann® Variobase® prosthetic components. Only suitable self-adhesive cementation systems for the material shall be used. Follow the instructions for use of both the prosthetic material and bonding material manufacturer (Straumann recommends Panavia™ F2.0 by Kuraray).

11) Bond the prosthetic restoration to the Straumann® Variobase® prosthetic components.

12) Immediately remove excess cement from the Straumann® Variobase® prosthetic components and polish the lower margin of the prosthetic restoration after the cement has set.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Warning

Torque values greater than 35 Ncm may result in failure of the abutment and/or implant. Torque values less than the recommended values may result in loosening of the abutment, which may lead to abutment and/or implant failure.

Please note: Once the Straumann abutment has been secured to the implant using the indicated torque, it should not be removed.

12. Further information

For additional information about the use of Straumann products, please contact your local Straumann sales representative. Additional information on Straumann products is available on the Straumann website (www.straumann.com). The following brochures provide additional guidance on the use of the Straumann prosthetic components and instruments:

- *Guideline for Cleaning, Disinfection and Sterilization for Straumann® Implant-borne Prosthetic Components*, 152.802

13. Please note

Practitioners must have knowledge of dental implantology and instruction in the handling of the Straumann product described herein ("Straumann Product") for using the Straumann Product safely and properly in accordance with these instructions for use.

The Straumann Product must be used in accordance with the instructions for use provided by the manufacturer. It is the practitioner's responsibility to use the device in accordance with these instructions for use and to determine, if the device fits to the individual patient situation.

The Straumann Products are part of an overall concept and must be used only in conjunction with the corresponding original components and instruments distributed by Institut Straumann AG, its ultimate parent company and all affiliates or subsidiaries of such parent company ("Straumann"), except if stated otherwise in these instructions for use. If use of products made by third parties is not recommended by Straumann in these instructions for use, any such use will void any warranty or other obligation, express or implied, of Straumann.

14. Validity

Upon publication of these instructions for use, all previous versions are superseded.

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Straumann® and/or other trademarks and logos from Straumann® mentioned herein are the trademarks or registered trademarks of Straumann Holding AG and/or its affiliates.

15. Availability

Some items of the Straumann® Dental Implant System are not available in all countries.

CEREC® is a registered trademark of Sirona Dental Systems GmbH, Germany.
Galileos is a brand used by Sirona Dental Systems GmbH,Germany.
Panavia™ is a registered trademark of Kuraray Co., Ltd. JP.

	Consult instructions for use Please follow the link to the e-IFU www.ifu.straumann.com
	Manufacturer
CE 0123	Straumann Products with the CE mark fulfill the requirements of the Medical Devices Directive 93/42/EEC
REF	Catalogue number
LOT	Batch code
	Do not re-use
NON STERILE	Non-sterile
	Do not use if package is damaged
URL	Ifu.straumann.com
Qty	Quantity symbol
Rx only	Caution: U.S. federal law restricts this device to sale by or on the order of a dental professional.

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14 Sterilization and Shelf Life

14.1 Sterilization

(b)(4)

[redacted]

14.2 Shelf Life

The Straumann Variobase for CEREC Abutments are provided non-sterile and do not have a defined shelf life.

14.3 Packaging

The Straumann Variobase for CEREC Abutments are provided non-sterile in a blister package. The packaging consists (b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9417; Released by CDRH on 04-25-2016

15 Biocompatibility

The Straumann Variobase Abutments for CEREC are permanent implants in contact with tissue/mucosal surfaces. (b)(4) [redacted] for previously submitted information demonstrating the biocompatibility of these devices.

.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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16 Software

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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17 Electrical Safety and Electromagnetic Compatibility

The subject devices are components of a passive dental implant system. They do not contain active elements, nor do they rely upon the use of active elements, so they pose no electrical safety risk. They are not a source of electromagnetic energy. Therefore, testing for electrical safety and electromagnetic compatibility are not applicable for these devices.

17.1 MRI Safety Information

Complete details of the MR compatibility testing (b)(4)

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4) Testing

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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APPENDIX 17-1: Test Report: (b)(4) Testing [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

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(b)(4) Third Party Testing

Records processed under FOIA Request # 2015-9417; Released by CDRH on 04-25-2016

18 Performance Testing – Bench

As previously described in this 510(k), the Straumann Variobase Abutments previously

(b)(4) Testing

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9417; Released by CDRH on 04-25-2016

(b)(4) Testing

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9417; Released by CDRH on 04-25-2016

(b)(4) Testing

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9417; Released by CDRH on 04-25-2016

(b)(4) Testing

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9417; Released by CDRH on 04-25-2016

APPENDIX 18-1: (b)(4) Testing [redacted] Test Report

(b)(4) Testing [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

APPENDIX 18-2: (b)(4) Testing [redacted] Testing

(b)(4) Testing

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9417; Released by CDRH on 04-25-2016

(b)(4) Testing [redacted]

sirdumann

(b)(4) [redacted] testing (b)(4) [redacted]

Variobase CEREC (b)(4) (b)(4) [redacted]

(b)(4) [redacted]

Test Plan
Test Report

Verification
Validation

(b)(4) Testing [redacted]

(b)(4) [redacted]

(b)(4) Testing

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(b)(4) Testing

Records processed under FOIA Request # 2015-9417; Released by CDRH on 04-25-2016

(b)(4) Testing [redacted]

sirdumann

(b)(4) [redacted] testing (b)(4) [redacted]

Variobase CEREC (b)(4) [redacted]

(b)(4) Testing [redacted]

Test Plan
Test Report

Verification
Validation

(b)(4) Testing [redacted]

(b)(4), (b)(6) Testing [redacted]

(b)(4) Testing

(b)(4) Testing

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(b)(4) Testing

(b)(4) Testing

APPENDIX 18-3: (b)(4) Testing [redacted] for Straumann Variobase for CEREC

Records processed under FOIA Request # 2015-9417; Released by CDRH on 04-25-2016
(b)(4) Testing [redacted]

Variobase for CEREC

(b)(4) Testing [redacted]

Test Plan
Test Report

Verification
Validation

(b)(4) Testing [redacted]

(b)(4), (b)(6) Testing [redacted]

(b)(4) Testing

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(b)(4) Testing

Records processed under FOIA Request # 2015-9417; Released by CDRH on 04-25-2016

19 Performance Testing – Animal

This section is not applicable as no animal testing was performed in the development of the proposed devices.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9417; Released by CDRH on 04-25-2016

20 Performance Testing – Clinical

This section is not applicable as clinical study results are not being submitted in this premarket notification.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9417; Released by CDRH on 04-25-2016

K151324 / S001

FDA CDRH DMC
AUG 13 2015
Received

straumann

August 12, 2015

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

Subject: **K151324 – Straumann® Variobase® for CEREC**
Response to Additional Information Request dated July 17, 2015

Dear Ms. Giles:

Straumann USA is submitting this response to FDA's Additional Information Request sent via email dated July 17, 2015 concerning K151324, Straumann® Variobase® for CEREC.

This response is structured with the associated checklist item number followed by FDA's comments in bold text followed by the Straumann response and applicable attachments.

Two copies of this response are provided; one copy is hardcopy and one copy is electronic on CD-ROM with a filename beginning with "001_." Both copies of the response are identical with the exception of the ink signature.

Straumann requests that the FDA keep and maintain confidential both the existence and the content of this response to the referenced Premarket Notification.

If you have any questions with regard to the information provided, please do not hesitate to contact me as identified below.

Sincerely,

(b)(6) [redacted]

Christopher Klaczyk
Director of Regulatory Affairs
(b)(4) [redacted]
Telephone: 978/747 2575

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

44

Records processed under FOIA Request # 2015-9417; Released by CDRH on 04-25-2016

straumann

August 12, 2015

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

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(b)(6) [redacted]

Christopher Klaczyk
Director of Regulatory Affairs
(b)(4) [redacted]
Telephone: 978/747 2575

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Deficiencies

[redacted]

(b)(4) Deficiencies

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Records processed under FOIA Request # 2015-9417; Released by CDRH on 04-25-2016

Attachment 1 – (b)(4) Deficiencies [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9417; Released by CDRH on 04-25-2016

K111421

FEB 17 2012

510(k) Summary

for

Sirona Dental Systems

Sirona Dental CAD/CAM System

1 Sponsor

Sirona Dental Systems GmbH

Fabrikstrasse 31

D-64625 Bensheim
Germany

Contact Person: Fritz Kolle
Telephone: 49 6251 16 32 94

Date Prepared: May 06, 2011

2 Device Name

Proprietary Name:	Sirona Dental CAD/CAM-System
Common/Usual Name:	Abutment, implant, dental, endosseous
Classification Names:	Endosseous dental implant abutment

3 Predicate Devices

Replace® NP, K091756, Brånemark®, K091756, Tissue level NN, K081005, OsseoSpeed™, K081666, Frialit® / Xive®, K032158, Osseotite K072642, Tapered Screw-Vent®, K060880, Nobel Active NP, K102436, Bone Level NC, K062129, Certain®, K073345.

Sirona Dental CAD/CAM System (K100152)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9417; Released by CDRH on 04-25-2016

4 Intended Use

The Sirona Dental CAD/CAM System is intended for use in partially or fully edentulous mandibles and maxillae in support of single or multiple-unit cement retained restorations. For the titanium bases SSO 3.5 L and SBL 3.3 L, the indication is restricted for replacement of single lateral incisors in the maxilla and lateral and central incisors in the mandible. The system consists of three major parts: TiBase, inCoris mesostructure, and CAD/CAM software. Specifically, the inCoris mesostructure and TiBase components make up a two-piece abutment which is used in conjunction with endosseous dental implants to restore the function and aesthetics in the oral cavity. The inCoris mesostructure may also be used in conjunction with the Camlog Titanium base CAD/CAM (types K2244.xxxx) (K083496) in the Camlog Implant System. The CAD/CAM software is intended to design and fabricate the inCoris mesostructure. The inCoris mesostructure and TiBase two-piece abutment is compatible with the following implants systems:

- Nobel Biocare Replace (K020646)
- Nobel Biocare Branemark (K022562)
- Friadent Xive (K013867)
- Biomet 3i Osseotite (K980549)
- Astra Tech Osseospeed (K091239)
- Zimmer Tapered Screw-Vent (K061410)
- Straumann SynOcta (K061176)
- Straumann Bone Level (K053088, K062129, K060958)
- Biomet 3i Certain (K014235, K061629)
- Nobel Biocare Active (K071370)

5 Device Description

The Sirona Dental CAD/CAM-System takes optical impressions and records the topographical characteristics of teeth, dental impressions, or stone models. Dental restorative prosthetic devices are manufactured using computer aided design and fabrication. The system also features the processing of mesostructures, a dental restorative prosthetic device used in conjunction with endosseous dental implant abutments.

The system that features the processing of mesostructures comprises

- Titanium bases TiBase and Camlog

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- inCoris ZI meso blocks
- Sirona Dental CAD/CAM Design and fabricating devices

Titanium bases are used as an implant prosthetic titanium base for adhesion to mesostructures to restore function and aesthetics in the oral cavity.

inCoris ZI meso blocks are used in manufacturing individually designed mesostructures, which are glued to a fitting titanium base after milling and sintering.

Sirona Dental CAD/CAM design and fabricating devices feature the processing of mesostructures, a dental restorative prosthetic device used in conjunction with endosseous dental implant abutments, i.e. it is an accessory to it. This component consists of the devices CEREC3, CEREC AC, inEos, inEos Blue, CEREC MCXL and inLab MCXL.

5.1 TiBase

5.1.1 Device Function

The Sirona TiBase is a premanufactured prosthetic component directly connected to dedicated endosseous dental implants and is intended for use as an aid in prosthetic rehabilitation.

The Sirona offering consists of the titanium base TiBase, the abutment screw and the scanbody. The parts are marketed non-sterile and for single use only.

The Sirona TiBase is bonded to an individually designed mesostructure, a ceramic prosthetic/restoration, that supports the final restoration. The mesostructure is milled from an inCoris ZI meso block with Sirona CAD/CAM milling machines CEREC or inLab, and sintered afterwards.

The two piece abutment is mounted onto the implant and fixed with a screw.

The scope of delivery contains a scanbody (ABS plastic) which is mounted on a TiBase in order to acquire the topographical surface of the area where the endosseous dental implant abutment is located with Sirona Dental CAD/CAM fabricating devices. From the acquired data the position of the implant can be calculated. After an optical impression has been taken the scanbody is removed.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Sirona TiBase devices are compatible with following systems (Table 1):

Table 1: Sirona TiBase Devices Compatibility

Sirona TiBase	Compatible System		
	Manufacturer	System	Diameter
(b)(4) [redacted]	[redacted]	[redacted]	3,5 mm
			4.3 mm
			5.0 mm
			6.0 mm
			3.4 mm
			4.1 mm
			3.5 mm
			4.8 mm
			6.5 mm
			3.5 S / 4.0 S mm
			4.5 / 5.0 mm
			3.4 mm
			3.8 mm
			4.5 mm
			5.5 mm
			3.4 mm
			4.1 mm

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9417; Released by CDRH on 04-25-2016

Sirona TiBase	Compatible System		
	Manufacturer	System	Diameter
(b)(4) [redacted]	[redacted]	[redacted]	5.0 mm
			3.5 mm
			4.5 mm
			5.7 mm
			3.5mm
			4.3 / 5.0mm
			3.3mm
			4.1 / 4.8mm
			3.4mm
			4.1mm
			5.0mm

5.1.2 Scientific Concept

The underlying scientific concept is the use of an already introduced technology of a [redacted] (b)(4) [redacted].

5.1.3 Physical and Performance Characteristics

5.1.3.1 Design

The TiBase devices have various diameters, are compatible with dedicated implant systems, and fit to compatible implants as provided in Table 2.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table 2: Implant Compatibility

TiBase	Implant-Manufacturer	Implant-System	510(k) Implant
(b)(4) [redacted]			

5.1.3.2 Material Used

(b)(4) [redacted]

5.1.3.3 Physical Properties

TiBase material composition and mechanical properties comply with ISO 5832-3:1996, Implants for surgery -- Metallic materials -- Part 3: (b)(4) [redacted] (b)(4) [redacted]

Sirona TiBase devices are compatible with systems listed in Table 1.

5.2 inCoris ZI meso

5.2.1 Device Description

The inCoris ZI meso offerings are blocks of various sizes from which individual dental mesostructures are grinded by milling machines (inLab MCXL, CEREC MCXL). The mesostructure is a part of a 2 part endosseous dental implant

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Records processed under FOIA Request # 2015-9417; Released by CDRH on 04-25-2016

abutment which comprises a titanium base and a zirconium oxide mesostructure. The connection geometries are prefabricated.

5.2.2 Scientific Concept

The underlying scientific concept is the use of an already introduced technology of a [redacted] (b)(4) [redacted].

5.2.3 Physical and Performance Characteristics

5.2.3.1 Design

The inCoris ZI meso are blocks of various sizes. The marketed ceramic is pre-sintered. One side of a block is mounted to a mandrel that will be inserted in the spindle's clamping chuck of the grinding machine. The connection geometry to titanium bases is prefabricated, i.e. already included in the shipped block. Connection geometries fit on Camlog (type K2244.xxxx) and Sirona (Tibase) titanium bases (Table 3 and Table 4).

Table 3: Sirona inCoris ZI meso - TiBase Devices Compatibility

Titanium Base			Ceramic Block		
TiBase (Sirona)	REF	Diameter	inCoris ZI meso (Sirona)	REF	Color inCoris ZI meso (Sirona)
NBRS 3.5	6282474	3,5 mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
NBRS 4.3	6282482	4.3 mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
NBRS 5.0	6282490	5.0 mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
NBRS 6.0	6282508	6.0 mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
NBB 3.4	6282516	3.4 mm	inCoris ZI	62 31 810	F0.5

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Titanium Base			Ceramic Block		
TiBase (Sirona)	**REF**	**Diameter**	**inCoris ZI meso (Sirona)**	**REF**	**Color inCoris ZI meso (Sirona)**
			meso L	62 31 836	F2
NBB 4.1	6282524	4.1 mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
SSO 3.5	6284231	3.5 mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
SSO 4.8	6284249	4.8 mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
SSO 6.5	6284256	6.5 mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
ATOS 3.5/4.0	6282532	3.5 S / 4.0 S mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
ATOS 4.5/5.0	6282540	4.5 / 5.0 mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
FX 3.4	6282433	3.4 mm	inCoris ZI meso S	62 31 802 62 31 828	F0.5 F2
FX 3.8	6282441	3.8 mm	inCoris ZI meso S	62 31 802 62 31 828	F0.5 F2
FX 4.5	6282458	4.5 mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
FX 5.5	6282466	5.5 mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
BO 3.4	6282557	3.4 mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Titanium Base			Ceramic Block		
TiBase (Sirona)	**REF**	**Diameter**	**inCoris ZI meso (Sirona)**	**REF**	**Color inCoris ZI meso (Sirona)**
BO 4.1	6282565	4.1 mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
BO 5.0	6282573	5.0 mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
ZTSV 3.5	6282581	3.5 mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
ZTSV 4.5	6282599	4.5 mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
ZTSV 5.7	6282607	5.7 mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
NB A 4.5	6308188	3.5mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
NB A 5.0	6308253	4.3 / 5.0mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
S BL 3.3	6308154	3.3mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
S BL 4.1	6308337	4.1 / 4.8mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
B C 3.4	6308048	3.4mm	inCoris ZI meso S	62 31 802 62 31 828	F0.5 F2
B C 4.1	6308097	4.1mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2

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Titanium Base			Ceramic Block		
TiBase (Sirona)	**REF**	**Diameter**	**inCoris ZI meso (Sirona)**	**REF**	**Color inCoris ZI meso (Sirona)**
B C 5.0	6308121	5.0mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2

Table 4: Sirona inCoris ZI meso - Camlog Devices Compatibility

Titanium Base			Ceramic Block		
Camlog	**REF**	**Dia-meter**	**inCoris ZI meso (Sirona)**	**REF**	**Color inCoris ZI meso (Sirona)**
K2244.3348	K2244.3348	3.3	inCoris ZI meso S	62 31 802 62 31 828	F0.5 F2
K2244.3848	K2244.3848	3.8	inCoris ZI meso S	62 31 802 62 31 828	F0.5 F2
K2244.4348	K2244.4348	4.3	inCoris ZI meso S	62 31 802 62 31 828	F0.5 F2
K2244.5048	K2244.5048	5.0	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
K2244.6048	K2244.6048	6.0	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2

5.2.3.2 Material Used

[redacted] (b)(4) [redacted]

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(b)(4)

[redacted]

5.2.3.3 Physical Properties

The final technical data of inCoris ZI meso are (after final sintering):

Density:	6.06 g/cm^3
Coefficient of thermal expansion (CTE):	11.0*10-6 K^{-1}
Flexural strength:	> 900 MPa
Fracture toughness (KIC):	5.9 MPa·m$^{1/2}$

5.3 Sirona Dental CAD/CAM Design and fabrication Devices

5.3.1 Device Description

The Sirona Dental CAD/CAM Design and fabricating devices for processing mesostructures includes

- Optical acquisition or recording of the topographical characteristics of dental impressions, or stone models using the devices Acquisition unit CEREC 3, CEREC AC, and stationary scanning system inEos Blue
- Design of mesostructures and processing the acquired or recorded data for these purposes using Sirona Dental CAD/CAM Software which runs on a CEREC 3, CEREC AC or PC. Design is performed by a dentist or dental technician
- Milling of the mesostructure using CEREC MCXL or inLab MCXL milling machines from ceramic blocks intended for dental restorations and mesostructures

The Sirona Dental CAD/CAM Design and fabricating devices also processes other dental restorations like crowns, bridge-frameworks, inlays, onlays all regulated under 21 CFR 872.3661, Optical Impression Systems for CAD/CAM, for such intended use.

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5.3.2 Scientific Concept

The underlying scientific concept is the use of CAD/CAM technology for the optical acquisition of the topographical characteristics of dental impressions, and models, the design of individual mesostructures using recorded data (CAD), and eventually fabricating (milling) these designed mesostructures (CAM).

5.3.3 Physical and Performance Characteristics

5.3.3.1 Design

Acquisition unit: the device consists of a camera for acquiring optical topographical characteristics of dental impressions. The recorded data are used for the design of individual mesostructures using CAD techniques specific to the dental field.

Fabricating devices: the devices mill the individual designed mesostructures from incoris ZI meso blocks. For this purpose the chucked block and the milling tools move according to prescribed trajectories to generate the shape which is intended to be milled.

5.3.3.2 Materials Used

Not applicable.

5.3.3.3 Physical Properties

Not applicable.

6 Summary of the technological characteristics

6.1 TiBase

All proposed and predicate titanium bases and screws are made of (b)(4), (b)(4) Connection interfaces to the implants are identical for each defined diameter and connection type. Connection interfaces to dental restorations differ in that proposed devices have an additional notch.

An extensive list is provided in Table 5.

6.2 inCoris ZI meso

Proposed and predicate (K100152) device are inCoris ZI meso.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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There has been no modification to inCoris ZI meso from Premarket Notification K100152. Specifically, the following aspects remain identical:

- Composition
- Material properties
- Thickness / design restrictions
- Shape and bonding surface of connection interfaces to Camlog and Sirona Tibase for Sirona inCoris ZI meso blocks
- Bonding material

InCoris ZI meso is bonded to titanium bases for supporting further dental restorations.

InCoris ZI meso material is made (b)(4) [redacted]. The composition of inCoris complies with ISO standard 13356:1997, "Implants for surgery, Ceramic materials based on [redacted]. Such compositions are classified as biocompatible by this standard.

An extensive list is provided in Table 6.

6.3 Sirona Dental CAD/CAM Design and fabrication Devices

There has been no modification to the Sirona Dental CAD/CAM Design and fabricating devices from Premarket Notification K100152. Specifically, the following aspects remain identical:

- optical impressions record topographical characteristics of teeth, dental impressions, or stone models for use in the computer aided design and fabrication of dental restorative prosthetic devices in conjunction with endosseous dental implant abutments, i.e. it is an accessory
- features the transfer of data of the optical impression to a remote milling machine via internet or exportation/importation of milling data

The software database of titanium bases has been extended to cover new additional titanium bases.

An extensive list is provided in Table 7.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table 5: Comparison of Sirona TiBase to Predicate Devices

Proposed Device TiBase	Predicate Device					Abutment and Screw made of Ti6Al4V	Identical connection geometry to abutments	Connection geometry Type	Connection geometry Anti-rotational features	Screw geometry
	Manufacturer	System	Diameter	Titanium Base	Predicate Devices K-Number					
(b)(4) [redacted]	b)(4) [redacted] o)(4)	(b)(4) [redacted]	3,5 mm	Nobel Biocare product catalog page 14. Product-No. 32376	K091756	yes	yes	Internal 3 tenons	yes	same
			4.3 mm	Product-No. 32377	K091756	yes	yes	Internal 3 te-	yes	same

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Proposed Device TiBase	Predicate Device					Abut-ment and Screw made of Ti6Al4 V	Iden-tical con-nec-tion geo-metry to abut-ments	Con-nec-tion geo-metry Type	Con-nec-tion geo-metry Anti-rota-tional fea-tures	Screw geo-metry
	Manu-facturer	System	Diameter	Titanium Base	Predicate Devices K-Number					
								nons		
(b)(4) [redacted]			5.0 mm	Product-No. 32378	K091756	yes	yes	Inter-nal 3 te-nons	yes	same
			6.0 mm	Product-No. 32375	K091756	yes	yes	Inter-nal 3 te-nons	yes	same

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Proposed Device TiBase	Predicate Device					Abutment and Screw made of Ti6Al4V	Identical connection geometry to abutments	Connection geometry Type	Connection geometry Anti-rotational features	Screw geometry
	Manufacturer	System	Diameter	Titanium Base	Predicate Devices K-Number					
(b)(4) [redacted]	[redacted]	[redacted]	3.4 mm	Nobel Biocare product catalog page 14. Product-No. 32396	K091756	yes	yes	External Hexagonal	yes	same
[redacted]	[redacted]	[redacted]	4.1 mm	Product-No. 32397	K091756	yes	yes	External Hexagonal	yes	same

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Proposed Device TiBase	Predicate Device					Abutment and Screw made of Ti6Al4V	Identical connection geometry to abutments	Connection geometry Type	Connection geometry Anti-rotational features	Screw geometry
	Manufacturer	System	Diameter	Titanium Base	Predicate Devices K-Number					
(b)(4) [redacted]	[redacted]	[redacted]	3.5 mm	Straumann product catalog page 51. Product-No. 048.505	K081005	yes	yes	external octagonal	yes	same
			4.8 mm	Product-No. 048.600 (p 55)	K081005	yes	yes	Internal Octagonal	yes	same
			6.5 mm	Product-No. 048.606	K081005	yes	yes	Inter-	yes	same

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Proposed Device TiBase	Predicate Device					Abut-ment and Screw made of Ti6Al4 V	Iden-tical con-nec-tion geo-metry to abut-ments	Con-nec-tion geo-metry Type	Con-nec-tion geo-metry Anti-rota-tional fea-tures	Screw geo-metry
	Manu-facturer	System	Diameter	Titanium Base	Predicate Devices K-Number					
				(p 62)				nal Octa-gonal		
(b)(4) [redacted]			3.5 S / 4.0 S mm	Product-No. 24285	K081666	yes	yes	Inter-nal Hexa-gonal	yes	same
[redacted]			4.5 / 5.0 mm	Product-No. 24235	K081666	yes	yes	Inter-nal Hexa-	yes	same

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Proposed Device TiBase	Predicate Device					Abutment and Screw made of Ti6Al4V	Identical connection geometry to abutments	Connection geometry Type	Connection geometry Anti-rotational features	Screw geometry
	Manufacturer	System	Diameter	Titanium Base	Predicate Devices K-Number					
								gonal		
(b)(4) [redacted]			3.4 mm	Friadent product catalog page 32. Product-No. 46-2132	K032158	yes	yes	Internal Hexagonal	yes	same
			3.8 mm	Product-No. 46-2142	K032158	yes	yes	Internal Hexagonal	yes	same

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Proposed Device TiBase	Predicate Device					Abut-ment and Screw made of Ti6Al4 V	Iden-tical con-nec-tion geo-metry to abut-ments	Con-nec-tion geo-metry Type	Con-nec-tion geo-metry Anti-rota-tional fea-tures	Screw geo-metry
	Manu-facturer	System	Diameter	Titanium Base	Predicate Devices K-Number					
(b)(4) [redacted]			4.5 mm	Product-No. 46-2152	K032158	yes	yes	Inter-nal Hexa-gonal	yes	same
			5.5 mm	Product-No. 46-2162	K032158	yes	yes	Inter-nal Hexa-gonal	yes	same
			3.4 mm	3i Biomet product catalog page 25.	K072642	yes	yes	Exter-nal	yes	same

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Proposed Device TiBase	Predicate Device					Abutment and Screw made of Ti6Al4V	Identical connection geometry to abutments	Connection geometry Type	Connection geometry Anti-rotational features	Screw geometry
	Manufacturer	System	Diameter	Titanium Base	Predicate Devices K-Number					
(b)(4) [redacted]	[redacted]	[redacted]		Product-No. MAP32G		yes	yes	Hexagonal External Hexagonal	yes	same
[redacted]	[redacted]	[redacted]	4.1 mm	Product-No. APP452G	K072642	yes	yes			
[redacted]	[redacted]	[redacted]	5.0 mm	Product-No. WPP552G	K072642	yes	yes	External Hexagonal	yes	same

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Proposed Device TiBase	Predicate Device					Abutment and Screw made of Ti6Al4V	Identical connection geometry to abutments	Connection geometry Type	Connection geometry Anti-rotational features	Screw geometry
	Manufacturer	System	Diameter	Titanium Base	Predicate Devices K-Number					
(b)(4) [redacted]	[redacted]	[redacted]	3.5 mm	Zimmer product catalog page 9. Product-No. ZOA342S	K060880	yes	yes	Internal Hexagonal	yes	same
[redacted]	[redacted]	[redacted]	4.5 mm	Product-No. ZOA442S	K060880	yes	yes	Internal Hexagonal	yes	same

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Proposed Device TiBase	Predicate Device					Abutment and Screw made of Ti6Al4V	Identical connection geometry to abutments	Connection geometry Type	Connection geometry Anti-rotational features	Screw geometry
	Manufacturer	System	Diameter	Titanium Base	Predicate Devices K-Number					
(b)(4) [redacted]	[redacted]	[redacted]	5.7 mm	Product-No. ZOA562S	K060880	yes	yes	Internal Hexagonal	yes	same
[redacted]	[redacted]	[redacted]	3,5mm	Nobel Biocare product Catalog page 71. Product-No. 34194	K102436	yes	yes	Internal Hexagonal	yes	same

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Proposed Device TiBase	Predicate Device					Abutment and Screw made of Ti6Al4V	Identical connection geometry to abutments	Connection geometry Type	Connection geometry Anti-rotational features	Screw geometry
	Manufacturer	System	Diameter	Titanium Base	Predicate Devices K-Number					
(b)(4) [redacted]	[redacted]	[redacted]	4,3 / 5,0mm	Product-No. 34198	K102436	yes	yes	Internal Hexagonal	yes	same
[redacted]	[redacted]	[redacted]	3,3mm	Straumann product Catalog Product-No. 022.2102	K062129	yes	yes	Internal 4 slots	yes	same

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Proposed Device TiBase	Predicate Device					Abutment and Screw made of Ti6Al4V	Identical connection geometry to abutments	Connection geometry Type	Connection geometry Anti-rotational features	Screw geometry
	Manufacturer	System	Diameter	Titanium Base	Predicate Devices K-Number					
(b)(4) [redacted]	[redacted]	[redacted]	4,1 / 4,8mm	Product-No. 022.4102	K062129	yes	yes	Internal 4 slots	yes	same
[redacted]	[redacted]	[redacted]	3,4mm	Biomet product Catalog page 5 Product-No. IMAP32G	K073345	yes	yes	Internal. Hexagonal	yes	same
[redacted]	[redacted]	[redacted]	4,1mm	Biomet product	K073345	yes	yes	Internal	yes	same

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Proposed Device TiBase	Predicate Device					Abut-ment and Screw made of Ti6Al4 V	Iden-tical con-nec-tion geo-metry to abut-ments	Con-nec-tion geo-metry Type	Con-nec-tion geo-metry Anti-rota-tional fea-tures	Screw geo-metry
	Manu-facturer	System	Diameter	Titanium Base	Predicate Devices K-Number					
				Catalog page 5 Product-No. IAPP452G				Hexa-gonal		
(b)(4) [redacted]			5,0mm	Biomet product Catalog page 5 Product-No. IWPP562G	K073345	yes	yes	Inter-nal Hexa-gonal	yes	same

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Table 6: Comparison of InCoris ZI meso to Predicate Device

	InCoris ZI meso	InCoris ZI meso (K100152)
Intended use	inCoris ZI meso blocks are used in manufacturing individually designed mesostructures, which are glued to a fitting titanium base after milling and sintering.	inCoris ZI meso blocks are used in manufacturing individually designed mesostructures, which are glued to a fitting titanium base after milling and sintering.
Application	inCoris ZI mesostructures can only be used for the intended titanium bases or implants. Allocation of the connection size to the respective titanium base can be determined by the scanbody set of the respective implant system. Please observe the indications and contraindications of the implant.	inCoris ZI mesostructures can only be used for the intended titanium bases or implants. Allocation of the connection size to the respective titanium base can be determined by the scanbody set of the respective implant system. Please observe the indications and contraindications of the implant.
Contra-Indications	• Insufficient oral hygiene • Insufficient space available • Bruxism • For mesostructure-geometry with angulation correction greater than 20° to the implant axis • For mesostructure-geometry with angulation correction to the implant axis for Camlog only • For individual tooth restorations with free end saddle • For restorations with a length to implant length ratio of more than 1:1.25	• Insufficient oral hygiene • Insufficient space available • Bruxism • For restorations with angulation correction to the implant axis • For individual tooth restorations with free end saddle • For restorations with a length to implant length ratio of more than 1:1.25
Technical Data		
Block-Material Composition	(b)(4) [redacted]	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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	InCoris ZI meso	InCoris ZI meso (K100152)
	(b)(4) [redacted]	
Density (sintered)	6.06 g/cm^3	6.06 g/cm^3
Coefficient of thermal expansion (CTE)	$11.0*10^{-6}$ K^{-1} (20 °C - 500 °C)	$11.0*10^{-6}$ K^{-1} (20 °C - 500 °C)
Flexural strength	> 900MPa	> 900MPa
Fracture toughness (K_{IC})	5.8 MPa·m$^{1/2}$	5.8 MPa·m$^{1/2}$
Grain Size	about 0.5 µm	about 0.5 µm
Bonding Material	(b)(4) [redacted]	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table 7: Comparison of Sirona Dental CAD/CAM Design and fabricating Devices to Predicate Devices

	Sirona Dental CAD/CAM Design and fabricating Devices	Sirona Dental CAD/CAM Design and fabricating Devices (K100152)
Used for	The Sirona Dental CAD/CAM-System is indicated for taking optical impressions to record the topographical characteristics of teeth, dental impressions, or stone models by computer aided design and fabrication in patients that require dental restorative prosthetic devices. The system also features the processing of mesostructures, a dental restorative prosthetic device used in conjunction with endosseous dental implant abutments. Sirona Dental CAD/CAM Design and fabricating devices feature the processing of mesostructures, a dental restorative prosthetic device used in conjunction with endosseous dental implant abutments, i.e. it is an accessory to it. Devices which feature the processing of mesostructures comprises CEREC3, CEREC AC, inEos, inEos Blue, CEREC MCXL and inLab MCXL	The Sirona Dental CAD/CAM-System is indicated for taking optical impressions to record the topographical characteristics of teeth, dental impressions, or stone models by computer aided design and fabrication in patients that require dental restorative prosthetic devices. The system also features the processing of mesostructures, a dental restorative prosthetic device used in conjunction with endosseous dental implant abutments. Sirona Dental CAD/CAM Design and fabricating devices feature the processing of mesostructures, a dental restorative prosthetic device used in conjunction with endosseous dental implant abutments, i.e. it is an accessory to it. Devices which feature the processing of mesostructures comprises CEREC3, CEREC AC, inEos, inEos Blue, CEREC MCXL and inLab MCXL
Used with	Sirona Dental CAI/CAM Hardware	Sirona Dental CAI/CAM Hardware
Controlling of recording process (CAI) (optical impression)	Yes	Yes
Processing the recorded	Yes	Yes

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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	Sirona Dental CAD/CAM Design and fabricating Devices	Sirona Dental CAD/CAM Design and fabricating Devices (K100152)
data (data of optical impression) (CAD)		
Export of milling data to milling machine	Yes	Yes
Administration of patient data	Yes	Yes
Further functions	Calibration of CAI/CAM hardware	Calibration of CAI/CAM hardware
Online capability	Option to upload/download the data from a web portal (Cerec Connect), to have CAI and CAM operating on two different locations connected via Internet	Option to upload/download the data from a web portal (Cerec Connect), to have CAI and CAM operating on two different locations connected via Internet
Scan Implant Interface/surface	Yes (or with mounted scanbody)	Yes (or with mounted scanbody)
Scan custom wax-up	Yes	Yes
Preparation of individual restoration ("meso-structure") to be mounted on the abutment	Yes	Yes
Bond of milled ziconia/ceramic individual meso-structure to metal abutment	Yes	Yes
Create of fitting crown to be mounted on top of meso-structure	Yes	Yes
Used with	Sirona Dental CAI/CAM Hardware	Sirona Dental CAI/CAM Hardware

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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	Sirona Dental CAD/CAM Design and fabricating Devices	Sirona Dental CAD/CAM Design and fabricating Devices (K100152)
Used for	CAD creation of dental restorations including inlays, onlay, venners, crowns, bridges and meso-structure to be mounted on top of abutments	CAD creation of dental restorations including inlays, onlay, venners, crowns, bridges and meso-structure to be mounted on top of abutments
Controlling of measurement process (CAI)	Yes	Yes
Processing the measurement data (CAD)	Yes	Yes
Export to milling machine	Yes	Yes
Administration of patient data	Yes	Yes
Further functions	Calibration of CAI/CAM hardware	Calibration of CAI/CAM hardware

7 Nonclinical Testing

According to FDA Guidance "Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments", May 12, 2004, [redacted] (b)(4) [redacted].

(b)(4) [redacted] (b)(4) [redacted]

8 Clinical Testing

Clinical testing is not required and has not been performed.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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9 Conclusion

Based on a comparison of intended use, indications, construction materials, principal of operations, features and technical data, the Sirona Dental CAD/CAM System which comprises of titanium bases TiBase, inCoris ZI meso blocks and Sirona Dental CAD/CAM Design and fabricating devices are safe and effective their intended use and perform as well as and are substantially equivalent to their Predicate Devices.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

Mr. Fritz Kolle
Sirona Dental Systems GmbH
Fabrikstrasse 31
Bensheim
Germany D-64625

FEB 17 2012

Re: K111421
Trade/Device Name: Sirona Dental CAD/CAM System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: February 14, 2012
Received: February 16, 2012

Dear Mr. Kolle:

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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9417; Released by CDRH on 04-25-2016

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, BS, MS, MBA
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9417; Released by CDRH on 04-25-2016

510(k) Number (if known):

Device Name: Sirona Dental CAD/CAM System

Indications for Use:

The Sirona Dental CAD/CAM System is intended for use in partially or fully edentulous mandibles and maxillae in support of single or multiple-unit cement retained restorations. The system consists of three major parts: TiBase, InCoris mesostructure, and CAD/CAM software. Specifically, the InCoris mesostructure and TiBase components make up a two-piece abutment which is used in conjunction with endosseous dental implants to restore the function and aesthetics in the oral cavity. The InCoris mesostructure may also be used in conjunction with the Camlog Titanium base CAD/CAM (types K2244.xxxx) (K083496) in the Camlog Implant System. The CAD/CAM software is intended to design and fabricate the InCoris mesostructure. The InCoris mesostructure and TiBase two-piece abutment is compatible with the following implant systems:

- Nobel Biocare Replace (K020646)
- Nobel Biocare Branemark (K022562)
- Friadent Xive (K013867)
- Biomet 3i Osseotite (K980549)
- Astra Tech Osseospeed (K091239)
- Zimmer Tapered Screw-Vent (K061410)
- Straumann SynOcta (K061176)
- Straumann Bone Level (K053088)
- Biomet 3i Certain (K014235)
- Nobel Biocare Active (K071370)

R S Betz DDS for Dr S. Runner
(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K111421

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Attachment 2 – (b)(4) Sterilization (b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Third Party Testing

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Records processed under FOIA Request # 2015-9417; Released by CDRH on 04-25-2016

Attachment 3 – Revised Variobase for CEREC Instructions For Use

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Instructions for use 701719
IFU Straumann(R) Variobase(R) for CEREC

7011719/A/00 03/15

Instructions for use: Straumann® Variobase® for CEREC®

NC RC RN WN

Institut Straumann AG, Peter-Merian-Weg 12, CH-4002 Basel/Switzerland, www.straumann.com

1. Product description

Abutments

Abutments are placed into dental implants to provide support for prosthetic reconstructions such as crowns and bridges.

Basal screws

Basal screws are used for the fixation of the abutment to the dental implant.

2. Intended use

Straumann® Variobase® Abutments are intended to be placed into Straumann dental implants to provide support for prosthetic reconstructions such as crowns.

3. Indications

The Straumann® Variobase® for CEREC® are titanium alloy abutments placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann® Variobase® for CEREC® abutments are indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations.

All digitally designed copings and/or crowns for use with the Straumann® Variobase® for CEREC® abutments are to be designed using Sirona inLab software (Version 3.65 or higher) or Sirona CEREC Software (Version 4.2 or higher) and manufactured using a Sirona CEREC or inLab MC X or MC XL milling unit.

Status:	Date: DD-MMM-YYYY	Time: CET		Signature: electronically signed acc. to 21CFR / Part 11	
Created:	24-MAR-2015 / 13:34:20			Andrea Schmidt	
Checked:	30-MAR-2015 / 10:31:22			Liane Sickert	
Released:	30-MAR-2015 / 10:34:22			Andrea Schmidt	
Type: BPZ	Number: 701719	Version: 01	Revision: B	SubDoc: 000	Current phase: n.a.	Pages: 1 of 7

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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4. Contraindications

Contraindicated in cases with known allergies or hypersensitivity to chemical ingredients of the following materials used: titanium (Ti), titanium alloy (Ti6Al7Nb (titanium-aluminum-niobium or TAN)).

5. Side effects, interactions and precautions; complications with Straumann implants

Information related to side effects, interactions and precautions; complications with Straumann implants should be provided to the patient.

6. Warnings

- Dental cement or any other material used for the attachment of prosthetic components should be processed as specified by the manufacturer. An implant is only to be restored with the corresponding original abutment compatible with that specific implant.
- The WN Variobase® for CEREC® is not compatible with the Sirona Gallileos Software. The use of the WN Variobase® for CEREC® in the guided surgery workflow may lead to a restoration which does not fit occlusally.

7. Caution/Precautions

- Straumann prosthetic devices must be secured to prevent aspiration during intraoral use.
- Failure to follow the procedures outlined in these instructions may lead to any or all of the following complications:
  - Aspiration or swallowing of components
  - Infection
  - Damage to the implant, abutment, components or tooling
  - Loosening of the abutment or other components
  - Improper final restoration or malfunction of the crown, bridge or other final prosthetics
  - Impairment of the patient's chewing function
  - Failure of the implant
  - Removal of the implant
- The Straumann® Variobase® for CEREC® is a single-use device.
- Always place temporary restorations out of occlusion. Use temporary cement for the attachment of temporary prosthetic restorations. Dental cement or any other material used for the attachment of prosthetic components should be processed as specified by the manufacturer.
- Place implant-borne restorations only in occlusion when the implant is completely osseointegrated.
- The Straumann Variobase for CEREC devices have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or image artifact in the MR environment. The safety of the Straumann Variobase for CEREC devices in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

8. Compatibility information

Straumann implants and the prosthetic components are available in a variety of configurations to meet your clinical needs. The label on each product uses abbreviations to help you identify whether a particular abutment or coping is compatible with the implant that you are restoring. The implant as well as the prosthetic component contains an identifier for the connection type, summarized in the table below.

Implant connection type	Compatible parts
NC (Narrow CrossFit®)	parts labeled NC
RC (Regular CrossFit®)	parts labeled RC
RN (Regular Neck)	parts labeled RN
WN (Wide Neck)	parts labeled WN

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9. Cleaning and disinfection

Straumann® Variobase® for CEREC® and components are non-sterile when delivered. Before placing the restoration in the patient's mouth, the product must be cleaned, disinfected and sterilized. Straumann recommends the following procedure for cleaning, disinfection and sterilization of abutments prior to use:

1. Clean the abutment rinsing it under running water while brushing the outer and inner side with adequate brushes.
2. The pre-treated product is to be cleaned/disinfected in an automated washer disinfector. Select the appropriate program according the manufacturer's instructions.

Consult the brochure *Guideline for Cleaning, Disinfection and Sterilization for Straumann® Implant-borne Prosthetic Components*, 152.802 for detailed information.

10. Sterilization

The finished restoration consisting of the Variobase for CEREC abutment with the milled restoration bonded in place may be sterilized unwrapped or can be placed in an accessory cassette and packaged twice in common sterilization wraps (paper/film/bags). Steam sterilize according to the following parameters.

Material	Method	Conditions
Variobase® for CEREC®, TAN and	Autoclave (moist heat)	North America: 132°C (270°F) 3 min
Screw, TAN	Displacement: gravity or fractionated vacuum	Europe, Other: 134°C (273°F) 5 min

Please note: User should ensure the use of the appropriate biological indicator for the sterilizer and parameters used.

Please note: The user should consult the coping/restoration material manufacturer's recommendations regarding sterilization.

Caution: Use devices immediately after sterilization. Do not store sterilized devices.

Consult the brochure *Guideline for Cleaning, Disinfection and Sterilization for Straumann® Implant-borne Prosthetic Components*, 152.802 for detailed information.

11. Procedure

Please note: A temporary restoration can be used prior to the insertion of the final components to maintain, stabilize and form the soft tissue during the healing phase.

Please note: In order to provide a dimensionally accurate original Straumann WN implant-abutment connection, the WN Variobase® for CEREC® is not compatible with the Sirona Gallileos Software. The use of the WN Variobase® for CEREC® in the guided surgery workflow may lead to a restoration which does not fit occlusally.

Use and compatibility of the Straumann® Variobase® for CEREC®:

- The Straumann® Variobase® for CEREC® can be used for screw- and cement-retained restorations.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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- When using a digital workflow the standard procedure according to the system provider instructions apply.
- Select the appropriate "Straumann compatible" Sirona Ti-base (e.g., for an NC Variobase® select the SBL 3.3 Ti-base in the inLab Software) from the implant library of the CADCAM system to design the restoration.
- The Straumann® Variobase® for CEREC® requires the use of Sirona inLab software (Version 3.65 or higher) or Sirona CEREC Software (Version 4.2 or higher) and a Sirona CEREC or inLab MC X or MC XL milling unit.
- The Straumann® Variobase® for CEREC® is compatible with the accessory components used in the Sirona CEREC® or inLab system (e.g., scanbodies, mill cutters).
- The abutment coronal design is compatible with material milling blocks having a pre-machined screw hole (e.g., IPS e.max CAD, inCoris ZI meso).

a.) Fabricate the prosthetic restoration

Please note: The instructions for use of the material manufacturer shall be followed.

Please note: The diameter or height of the Straumann® Variobase® for CEREC® must not be reduced, e.g. by grinding.

1) Fix the abutment either intraorally to the implant or extraorally to the implant analog on the master cast by tightening the basal screw hand-tight.
2) Insert the scan-body to the Straumann® Variobase® for CEREC®.
3) Proceed with an intraoral scan or scan the master cast to create a digital working model.
4) Select a comparable third party Ti-base from the implant library of the CADCAM system to design the restoration.
5) Process and finalize the prosthetic restoration according to the material manufacturer's instructions for use. Always finalize the crown or coping prior to bonding to the Straumann® Variobase® for CEREC®.

b.) Bonding the prosthetic restoration onto the abutment

Please note: Only the surfaces of the Straumann® Variobase® for CEREC® intended for gluing with a mesostructure or anatomic reduced crown must be sandblasted (50 µm aluminium oxide, max. 2 bar).

Please note: Prior to boding a fit test should be performed either on a model or intraorally.

1) Clean the abutment with alcohol or steam.
2) Fix the abutment to the implant analog or polishing tool by tightening the basal screw hand-tight.
3) Seal the screw channel with wax.
4) Apply self-adhesive dental cement on the Straumann® Variobase® prosthetic components. Only suitable self-adhesive cementation systems for the material shall be used. Follow the instructions for use of both the dental material and bonding material manufacturer. (Straumann recommends Panavia™ F2.0 by Kuraray).
5) Bond the prosthetic restoration to the Straumann® Variobase® prosthetic components.
6) Immediately remove excess cement from the Straumann® Variobase® prosthetic components.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9417; Released by CDRH on 04-25-2016

7) Optional for cement-retained restorations: Make a crown following the standard procedure according to the material manufacturer's instructions and finalize it.
8) Clean the restoration prior to further processing.

c.) Insertion

1) Remove the restoration form the master cast or the implant analog.
2) Clean, disinfect and sterilize the device as described in sections 9 and 10 of these instructions for use.
3) Remove the healing cap, closure screw or temporary restoration.
4) Clean and dry the interior of the implant and the abutment thoroughly.

   For screw-retained prosthetic solutions:

5) Place the sterilized restoration into the patient's mouth. All components should be placed carefully using tweezers. Straumann® Variobase® prosthetic components are inserted using a Straumann® SCS Screwdriver.
6) Make sure that the retentive elements of the implant-abutment connection are properly aligned.
7) Use the screw delivered with the abutment to screw the abutment into the dental implant.

   Please note: Always ensure that the surfaces of threads and screw heads are clean and that a new screw is used for the restoration.

8) Tighten the screws with the respective driver along with the Ratchet (046.119) and the Torque Control Device (046.049). The respective torque is described in the table below:

Device type	Tightening torque	Special considerations
Abutments (permanent)	35 Ncm	n/a
Temporary abutments	15 – 35 Ncm	Tighten only to 35 Ncm if the implant is fully osseointegrated
Components on implant analog	Hand-tight	n/a

9) Close the screw channels with cotton and a sealing compound (e.g. gutta-percha or composite restorative material). This allows a later removal of the Straumann® Variobase® prosthetic components in case a crown replacement is necessary.

   Optional for cement-retained restorations:

10) Apply self-adhesive dental cement on the Straumann® Variobase® prosthetic components. Only suitable self-adhesive cementation systems for the material shall be used. Follow the instructions for use of both the prosthetic material and bonding material manufacturer (Straumann recommends Panavia™ F2.0 by Kuraray).
11) Bond the prosthetic restoration to the Straumann® Variobase® prosthetic components.
12) Immediately remove excess cement from the Straumann® Variobase® prosthetic components and polish the lower margin of the prosthetic restoration after the cement has set.

Warning

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Torque values greater than 35 Ncm may result in failure of the abutment and/or implant. Torque values less than the recommended values may result in loosening of the abutment, which may lead to abutment and/or implant failure.

Please note: Once the Straumann abutment has been secured to the implant using the indicated torque, it should not be removed, except where a crown replacement is necessary. Never reuse a basal screw after it has been tightened.

12. Further information

For additional information about the use of Straumann products, please contact your local Straumann sales representative. Additional information on Straumann products is available on the Straumann website (www.straumann.com). The following brochures provide additional guidance on the use of the Straumann prosthetic components and instruments:

- *Guideline for Cleaning, Disinfection and Sterilization for Straumann® Implant-borne Prosthetic Components*, 152.802

13. Please note

Practitioners must have knowledge of dental implantology and instruction in the handling of the Straumann product described herein ("Straumann Product") for using the Straumann Product safely and properly in accordance with these instructions for use.

The Straumann Product must be used in accordance with the instructions for use provided by the manufacturer. It is the practitioner's responsibility to use the device in accordance with these instructions for use and to determine, if the device fits to the individual patient situation.

The Straumann Products are part of an overall concept and must be used only in conjunction with the corresponding original components and instruments distributed by Institut Straumann AG, its ultimate parent company and all affiliates or subsidiaries of such parent company ("Straumann"), except if stated otherwise in these instructions for use. If use of products made by third parties is not recommended by Straumann in these instructions for use, any such use will void any warranty or other obligation, express or implied, of Straumann.

14. Validity

Upon publication of these instructions for use, all previous versions are superseded.

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Straumann® and/or other trademarks and logos from Straumann® mentioned herein are the trademarks or registered trademarks of Straumann Holding AG and/or its affiliates.

15. Availability

Some items of the Straumann® Dental Implant System are not available in all countries.

CEREC® is a registered trademark of Sirona Dental Systems GmbH, Germany.

Galileos is a brand used by Sirona Dental Systems GmbH,Germany.

Panavia™ is a registered trademark of Kuraray Co., Ltd. JP.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Deutsch

English

Rx only Caution: U.S. federal law restricts this device to sale by or on the order of a dental professional.

Francais

Italiano

Espãnol

Portugués

Importador: Straumann Brasil Ltda
Rua Funchal 263 (cj. 121 – 124)
Vila Olimpia04551-060 São Paulo (SP)/Brasil
CNPJ 04.184.175/0001-57
Responsável Técnico: Fernanda Martins Lanzoni - CRF/SP: 28.047
Registro ANVISA 800765100xx

	Consult instructions for use Please follow the link to the e-IFU www.ifu.straumann.com
	Manufacturer
CE 0123	Machinery Directive 2006/42/EC, or Low Voltage Directive, or Electromagnetic Compatibility Directive
REF	Catalogue number
LOT	Batch code
	Do not re-use
NON STERILE	Non-sterile
	Do not use if package is damaged
URL	ifu.straumann.com
Qty	Quantity symbol

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Attachment 4 – (b)(4) [redacted] Instructions For Use

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records processed under FOIA Request # 2015-9417; Released by CDRH on 04-25-2016

Attachment 5 –(b)(4) [redacted] Instructions For Use

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records processed under FOIA Request # 2015-9417; Released by CDRH on 04-25-2016

Attachment 6 – Revised 510(k) Summary

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9417; Released by CDRH on 04-25-2016

6 510(k) Summary

K151324

6.1 Submitter's Contact Information

Submitter Name:	Straumann USA, LLC (on behalf of Institut Straumann AG)
Address:	60 Minuteman Road
	Andover, MA 01810
Phone Number:	1-978-747-2575
Fax Number:	1-978-747-0023
Contact Person:	Christopher Klaczyk
Date of Submission:	May 15, 2015

6.2 Name of the Device

Trade Name:	Straumann® Variobase® for CEREC®, Abutment Models RN, WN, RC, NC
Common Name:	Dental Implant Abutment
Classification Name:	Abutment, Implant, Dental, Endosseous
Regulation & Class:	21 CFR §872.3630, Class II
Product Code:	NHA

6.3 Predicate Device

K142890, Straumann® Variobase® Abutments, Models NNC, RN, WN, RC, NC

6.4 Device Description

The Straumann® Variobase® for CEREC® abutments provide the interface for copings or crowns designed and milled using the Sirona CEREC system with four of the Straumann dental implant platforms: RN (Regular Neck), WN (Wide Neck), RC (Regular CrossFit®), and NC (Narrow CrossFit®). The Straumann® Variobase® for CEREC® abutments are pre-manufactured (stock) abutments, sometimes referred to as "Ti-bases," made from a titanium-aluminum-niobium (TAN) alloy. The coronal portion is designed to interface with the pre-machined mounting hole in the milling blanks compatible with the Sirona CEREC MC X and MC XL prosthetic milling systems, and the base portion is available in four models to fit the four Straumann® dental implant platforms listed above. The new components introduced in this 510(k) are shown below.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Straumann® Variobase® for CEREC® Abutments			
RN	WN	RC	NC

Catalog Number	*Description*
022.0019	RN Variobase® for CEREC®
022.0020	WN Variobase® for CEREC®
022.0024	RC Variobase® for CEREC®
022.0025	NC Variobase® for CEREC®
022.0045	RN/WN Basal screw for Variobase®*

6.5 Intended Use

The Straumann® Variobase® for CEREC® are titanium alloy abutments placed onto Straumann® dental implants to provide support for customized prosthetic restorations. Straumann® Variobase® for CEREC® are indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations.

All copings and/or crowns for use with the Straumann® Variobase® for CEREC® abutments are to be digitally designed using Version 3.6 or higher of the Sirona inLab software and a Sirona MC X or MC XL milling unit following the instructions for use of those systems.

6.6 Substantial Equivalence and Performance Testing

The Straumann® Variobase® for CEREC® are made of the same TAN alloy material and the same base design as Straumann® Variobase® Abutments previously cleared for the Straumann® implant platforms RN, WN, RC and NC. The only difference is that the coronal portion of these abutments has been designed to interface with the milling blanks used to create copings and crowns with the Sirona CEREC® CAD/CAM system. The new design assures dimensional matching of the CEREC® restorations with the Straumann Variobase for CEREC ®abutments and provides an interlocking feature to augment the cemented adhesion of the restoration onto the abutment. The following performance testing was submitted in this 510(k) to support substantial equivalence:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9417; Released by CDRH on 04-25-2016

FEATURE	SUBJECT DEVICE Straumann Variobase for CEREC Abutments	PREDICATE DEVICE Straumann Variobase Abutments (K142890)	EQUIVALENCE DISCUSSION
Intended Use	Intended to be placed into Straumann dental implants to provide support for prosthetic reconstructions such as crowns.	Prosthetic components directly connected to the endosseous dental implant are intended for use as an aid in prosthetic rehabilitations.	Substantially equivalent
Indications for Use	The Straumann Variobase for CEREC are titanium alloy abutments placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann Variobase for CEREC abutments are indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations. All digitally designed copings and/or crowns for use with the Straumann Variobase for CEREC abutments are to be designed using Version 3.6 or higher of the Sirona inLab software and a Sirona MC X or MC XL milling unit.	The Straumann® Variobase™ Abutment is a titanium base placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann® Variobase™ Abutments are indicated for screw-retained single tooth or cement- retained single tooth and bridge restorations. All digitally designed copings and/or crowns for use with the Straumann® Variobase™ Abutment system are intended to be sent to Straumann for manufacture at a validated milling center.	Different workflows used to design and fabricate the restorations. Coronal aspect of proposed device is designed to interface with copings/crowns fabricated from milling blanks containing pre- machined holes for use with the CEREC CADCAM system. Substantial equivalence based on design validation testing.

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FEATURE	SUBJECT DEVICE Straumann Variobase for CEREC Abutments	PREDICATE DEVICE Straumann Variobase Abutments (K142890)	EQUIVALENCE DISCUSSION
Contraindications	Patients with known allergies or hypersensitivity to chemical ingredients of the following materials used: titanium (Ti), titanium alloy Ti6Al7Nb (titanium-aluminum-niobium or TAN)	Allergies or hypersensitivity to materials used: Titanium alloy Ti-6Al-7Nb (titanium- aluminum-niobium or TAN).	Same
Ti-base Material	Titanium-Aluminum-Niobium alloy (Ti-6Al-7Nb)	Titanium-Aluminum-Niobium alloy (Ti-6Al-7Nb)	Same
Abutment Diameter (base)	4.5 mm – 7.0 mm	3.8 mm – 7.0 mm	Substantially equivalent Proposed device models do not include NNC (3.8 mm dia)
Abutment Height	4.7 mm	3.5 – 4.5 mm	Substantially equivalent
Coping/ Crown Material	Compatible with any milling blanks cleared for use with the CEREC MC X and MC XL milling systems (i.e., containing the pre-machined mounting hole). Currently available: inCoris ZI meso (K123664) Ivoclar IPS e.max CAD (K132209) Ivoclar Telio CAD (K093708)	TraditionalWorkflow: Type 4 Metals (ISO 22674) IPS e.max® Press Ceramic Digital Workflow: polycon® ae (temporary) zerion® (permanent) IPS e.max® CAD Ceramic (permanent) coron® (permanent)	Substantially equivalent All materials to be used for coping/crown have previously been cleared and are not the subject of this 510(k).
Design Workflow	Per the Sirona CEREC InLab, software version 3.6 or later	Wax-up or Open CAD	Substantially equivalent

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FEATURE	SUBJECT DEVICE Straumann Variobase for CEREC Abutments	PREDICATE DEVICE Straumann Variobase Abutments (K142890)	EQUIVALENCE DISCUSSION
Manufacturing Workflow	Per the Sirona Cerec MC X and MC XL milling systems	Traditional casting or pressing or Straumann Milling	Substantially equivalent
Mode of Attachment	Screw-retained or cement retained	Screw-retained or cement retained	Same
Reusable	No	No	Same

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- Dimensional verification using CEREC® e.max blocks, which confirmed the appropriate fit of the milled coping on the abutment
- Worst case dynamic fatigue testing demonstrating compliance with the minimum required fatigue properties of the Straumann® Variobase® for CEREC® abutments with cemented e.max CADDAM coping
- Process validation of the Straumann® Variobase® for CEREC® within the Sirona CEREC® InLab workflow

There have been no changes to the materials, packaging, or recommended sterilization method/parameters for these devices as compared to the predicate devices.

6.7 Conclusion

The documentation submitted in this premarket notification demonstrates that the Straumann® Variobase® for CEREC® abutments are substantially equivalent to the predicate Straumann® Variobase® Abutments and do not pose new issues of safety and effectiveness when used as labeled.

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Attachment 7 – Test (b)(4) [redacted]

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Form

(b)(4)

straumann

(b)(4) testing (b)(4) Variobase CEREC Abutments

(b)(4)

Test Plan
Test Report

Verification
Validation

(b)(4)

(b)(4), (b)(6)

(b)(4) Testing

(b)(4) Testing

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