DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

October 28, 2016

OSSTEM Implant Co., Ltd
% David Kim
Manager
HiOSSEN Inc.
85 Ben Fairless Dr.
Fairless Hills, Pennsylvania 19030

Re: K160519
Trade/Device Name: Link Abutment for CEREC
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: September 28, 2016
Received: September 28, 2016

Dear David Kim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

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

Sincerely yours,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K160519

Device Name : Link Abutment for CEREC

Indication for use :
The Link Abutment for CEREC is titanium alloy abutments placed onto HIOSSEN dental implants to provide support for customized prosthetic restorations. Link Abutment for CEREC is indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations.

• Link abutment for CEREC
All digitally designed copings and/or crowns for use with the Link abutment for CEREC is to be scanned using Sirona CEREC AC or CEREC AF or CEREC AI, designed using Sirona inLab software (Version 3.65) or Sirona CEREC Software (Version 4.2) and manufactured using a Sirona CEREC or inLab MC X or MC XL milling unit. CAD/CAM manufacturing/milling occurs at dental laboratories per the design limitations of the Sirona CEREC.

Prescription Use___X____ (Per 21CFR801 Subpart D) OR Over-The-Counter Use _____. (Per 21CFR807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

Date: October 28, 2016

- Submitter's Name: OSSTEM Implant Co., Ltd.
- Address : 66-16, Bansong-ro 513beon-gil, Haeundae-gu, Busan, Republic of Korea
- Contact: Mr. Hee Kwon Son
- Phone: +82 51 850 2575

- Correspondent's Name: HIOSSEN Inc.
- Address: 85 Ben Fairless Dr. Fairless Hills, PA 19030
- Contact: DAVID KIM
- Phone: 267 759 7031

2. Device:

Trade or (Proprietary) Name :	Link Abutment for CEREC
Common or usual name :	Dental Abutment
Classification Name :	Endosseous dental implant abutment 21CFR872.3630 Class II NHA

3. Predicate Device(s):

Primary Predicate(s)

- ET/SS IMPLANT SYSTEM, OSSTEM IMPLANT CO.,LTD. - K120847

Reference Predicate(s)

- Straumann® Variobase® for CEREC®, Abutment Models RN, WN, RC, NC, Straumann USA, LLC, - K151324
- Sirona Dental Systems GmbH, Sirona Dental CAD/CAM System cleared under K111421;
- Sirona Dental Systems GmbH, Sirona Dental CAD/CAM System cleared under K100152;

4. Description:

The Link Abutment for CEREC provide the interface for mesostructure designed and milled using the Sirona CEREC system with HIOSSEN Implant System (K140934) The Link Abutment for CEREC is pre-manufactured (stock) abutment made from a titanium alloy (ASTM F 136). The Link Abutment for Cerec is a Ti-base abutment design consisting of the Link Abutment and Sirona ceramic mesostructure.
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

The Link Abutment for CEREC & superstructure must be sterilized in an autoclave (gravity displacement) at 132°C for 15 minutes before use. After the steam sterilization, the abutments & superstructure should be dried for 15 minutes before use.

Design limitation for Superstructure

(Unit: mm)

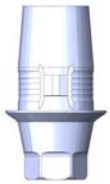
Superstructure design limitation			
Range (Diameter)	Range (Height)	Range (Wall thickness)	Range (Angle)
4.2 ~ 15	6 ~ 15	Min. 0.275	0 ~20°

Item	Content		
Link Abutment for CEREC	Material	Titanium Alloy (Ti-6Al-4V)	
	Gingival heights	0.5mm	
	type of connection	11° Morse taper internal connection	
		Mini Connection	Hex, Non-Hex
		Regular Connection	Hex, Non-Hex
	Diameter	Ø 4.5mm	
	Post Height	4.7mm	

- Substantial Equivalence Matrix

Part Name	Link Abutment for CEREC	Primary Predicate	Reference predicate
		Transfer Abutment	Straumann Variobase for CEREC
510K	K160519	K120847	K151324
Material	Titanium Alloy	Titanium Alloy	Titanium-Aluminum-Niobium alloy (Ti-6Al-7Nb)
Manufacturer	OSSTEM Implant Co., Ltd.	OSSTEM Implant Co., Ltd.	Institut Straumann AG

Indication for use	The Link Abutment for CEREC is titanium alloy abutments placed onto HIOSSEN dental implants to provide support for customized prosthetic restorations. Link Abutment for CEREC is indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations. • Link abutment for CEREC All digitally designed copings and/or crowns for use with the Link abutment for CEREC is to be scanned using Sirona CEREC AC or CEREC AF or CEREC AI, designed using Sirona inLab software (Version 3.65) or Sirona CEREC Software (Version 4.2) and manufactured using a Sirona CEREC or inLab MC X or MC XL milling unit. CAD/CAM manufacturing/milling occurs at dental laboratories per the design limitations of the Sirona CEREC.	The ET/SS Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading. The abutment is intended for use with a dental implant fixture to provide support for prosthetic restorations such as crowns, bridges, or overdenture.	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 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.
Diameter	4.5mm	4.6 mm. 5.0 mm, 6.0 mm, 7.0 mm	4.5 mm – 7.0 mm
Post Height	4.7mm	4.0 mm , 5.5 mm, 7.0 mm	4.7mm

Implant to abutment connection type / Connection mode	HIOSSEN dental implants; ETIII SA Fixture ETIII SA Ultra-Wide Fixture ETII SA Fixture 11° Morse taper internal connection Mini (Hex, non Hex) Regular (Hex, non Hex)	HIOSSEN dental implants; ETIII SA Fixture ETIII SA Ultra-Wide Fixture ETII SA Fixture 11° Morse taper internal connection Mini (Hex, non Hex) Regular (Hex, non Hex)	Straumann dental implant platforms: RN (Regular Neck),WN (Wide Neck), RC (Regular CrossFit®), and NC (Narrow rossFit®)
Restoration angulations	20°	0°	20°
Design			
mesostructure	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)	–	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)
Design Workflow	Per the Sirona CEREC InLab, software version 3.65	–	Per the Sirona CEREC InLab, software version 3.6 or later
Manufacturing Workflow	Per the Sirona Cerec MC X and MC XL milling systems	–	Per the Sirona Cerec MC X and MC XL milling systems
S E	Link Abutment for CEREC is almost same with Straumann Variobase for CEREC except shape, connection structure, and material but connection structure and material are exactly same with Transfer Abutment		

The Link Abutment for CEREC is compatible with the following previously cleared materials:
• inCoris ZI, L size blank (Sirona inCoris ZI meso zirconium dioxide, ZrO2) cleared to market per K062509 and K123664
• IPS e.max CAD Abutment Solutions (Ivoclar IPS e.max CAD lithium disilicate glass-ceramic, LS2) cleared to market per K132209
• Telio CAD (Ivoclar Telio CAD polymethylmethacrylate, PMMA) cleared to market per K093708

The Link Abutment for CEREC abutments are compatible with mesostructure fabricated using Sirona Dental CAD/CAM System

7. Indications for Use Statement

The Link Abutment for CEREC is titanium alloy abutments placed onto HIOSSEN dental implants to provide support for customized prosthetic restorations. Link Abutment for CEREC is indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations.
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8. Summary of nonclinical testing

Fatigue testing was considered according to the “Guidance for industry and FDA staff Class II Special Controls Guidance Document Root-form Endosseous Dental Implants and Endosseous Dental Abutment” with the worst case scenario. Sterilization validation was conducted according to ISO 17665-1:2006. Biocompatibility for the Link Abutment Ti-base component is demonstrated by the reference to K120847. All non-clinical testing was conducted for the subject device.

9. Summary of clinical testing

No clinical studies are submitted

10. Conclusions

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807**,** and based on the information provided in this premarket notification OSSTEM CO., LTD. concludes that Link Abutment for CEREC is substantially equivalent to the predicate devices as described herein.