510(K) SUMMARY

MAR 2 9 2013

IPS e.max Press Abutment Solutions for Nobel Biocare
K124008

Contact: Donna Marie Hartnett

Company: Ivoclar Vivadent, Inc. 175 Pineview Drive, Amherst, NY 14228
(716) 691-0010

Date Prepared: March 7, 2013

Proprietary Name: IPS e.max Press Abutment Solutions for Nobel Biocare

Classification Name: Abutment, Implant, Dental, Endosseous

Classification Code/Reg: NHA / 872.3630

Predicate Devices: IPS e.max Press Abutment Solutions K120053)

Device Description: IPS e.max Press will be used to press full ceramic pressed hybrid abutment crowns, or a customized hybrid abutment part which are luted on to recommended titanium connector abutments.

The predicate device to which IPS e.max Press Abutment Solutions for Nobel Biocare has been compared is IPS e.max Press Abutment Solutions (K120053). The materials are identical as to chemical composition, performance data and indications for use, except that the predicate device was cleared for use with certain identified Straumann dental implant systems. The subject device has been tested to provide evidence of its expanded compatibility with Nobel Biocare dental implant systems as stated in the Intended Use section below.

The comparison shows that the subject device is substantially equivalent to the predicate device.

Intended Use:
IPS e.max® Press Abutment Solutions for Nobel Biocare is intended for use in partially or fully endentuous mandibles and maxillae in support of single or multiple-unit cement retained restorations.

IPS e.max Press Abutment Solutions for Nobel Biocare is recommended for the fabrication of:

- Hybrid abutments for single-tooth restorations
- Hybrid abutment crowns for restorations

The following Ti bases and implant bodies are intended to be used with IPS e.max Press Abutment Solutions for Nobel Biocare.

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Implant manufacturer	**Implant system, diameter**	**Compatible Ti base (abutment), dimensions** gingiva height = GH height = HTi
Nobel Biocare	NobelReplace Tapered NP Ø 3.5mm, Length 8, 10, 11.5, 13, 16 mm NobelReplace Tapered RP Ø 4.3mm, Length 8, 10, 11.5, 13, 16 mm NobelReplace Tapered WP Ø 5.0mm, Length 8, 10, 11.5, 13, 16 mm NobelReplace Tapered 6.0 Ø 6.0mm, Length 8, 10, 11.5, 13, 16 mm Replace Select Tapered NP Ø 3.5mm, Length 8, 10, 11.5, 13, 16 mm Replace Select Tapered RP Ø 4.3mm, Length 8, 10, 11.5, 13, 16 mm Replace Select Tapered WP Ø 5.0mm, Length 8, 10, 11.5, 13, 16 mm Replace Select Tapered 6.0 Ø 6.0mm, Length 8, 10, 11.5, 13 mm (K050705)	Snappy Abutment 4.0 internal tri-channel NP, RP, WP, 6.0 HTI 4.0 - 5.5mm GH 0.5 - 1.5mm (K062749)

Technological Characteristics: The device design, i.e. delivery form, and intended use of IPS e.max Press Abutment Solutions for Nobel Biocare and the predicate device are the same. The composition of the subject device is identical to the predicate.

Description of the performance aspects
Material Composition: Lithium disilicate glass ceramic

Mechanical Properties: Fatigue tests under dynamic loading according to ISO 14801:2007 were completed using Nobel Biocare Replace Select Tapered TiU NP implant, Ø=3,5 mm, l=11.5mm and Snappy abutment 4.0 NobelReplace NP 0.75

IPS e.max Press can be applied as abutment on which a crown is luted (two part solution) or as abutment crown (one part solution).

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Implant to Abutment Compatibility: Not applicable. The interface between implant and abutment is confirmed by the titanium sleeve. By applying the heat/press technique IPS e,max Press can be processed individually on every indicated titanium sleeve.

Corrosion Testing: Not applicable – components do not consist of dissimilar metals.

Modified Surfaces: Not applicable.

Clinical Studies: Clinical testing is not required and has not been performed.

Testing Summary: The device was tested in accordance with ISO14801:2007 for Dynamic fatigue performance applicable to endosseous implant systems and the results from testing demonstrate that IPS e.max Press Abutment Solutions for Nobel Biocare is substantially equivalent to the predicate device.

The following Ti bases are intended to be used with IPS e.max Press Abutment Solutions for Nobel Biocare.

Implant manufacturer	**Implant system, diameter**	**Connection Platform**	**Compatible Ti base (abutment) dimensions** gingiva height = GH height = HTi
Nobel Biocare	NobelReplace Tapered NP Ø 3.5mm, Length 8, 10, 11.5, 13, 16 mm NobelReplace Tapered RP Ø 4.3mm, Length 8, 10, 11.5, 13, 16 mm NobelReplace Tapered WP Ø 5.0mm, Length 8, 10, 11.5, 13, 16 mm NobelReplace Tapered 6.0 Ø 6.0mm, Length 8, 10, 11.5, 13, 16 mm Replace Select Tapered NP Ø 3.5mm, Length 8, 10, 11.5, 13, 16 mm Replace Select Tapered RP Ø 4.3mm, Length 8, 10, 11.5, 13, 16 mm Replace Select Tapered WP Ø 5.0mm, Length 8, 10, 11.5, 13, 16 mm Replace Select Tapered 6.0 Ø 6.0mm, Length 8, 10, 11.5, 13 mm (K050705)	Tri-Channel	Snappy Abutment 4.0 internal tri-channel NP, RP, WP, 6.0 HTI 4.0 - 5.5mm GH 0.5 - 1.5mm (K062749)

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

March 29, 2013

Ms. Donna Marie Hartnett
Director Quality Assurance / Regulatory Affairs
Ivoclar Vivadent, Incorporated
175 Pineview Drive
AMHERST NY 14228

Re: K124008
Trade/Device Name: IPS e.max® Press – Abutment Solutions for Nobel Biocare
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: December 26, 2012
Received: December 31, 2012

Dear Ms. Hartnett:

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

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

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

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

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

Sincerely yours,

Kwame O. Ulmer-S for

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

Enclosure

Indications for Use

510(k) Number (if known): : K124008

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Prescription Use X AND/OR (Part 21 CFR 801 Subpart D)

Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheena A. Green -S
2013.03.27 11:06:35 -04'00' for M. Susan Runner, DDS, MA

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

510(k) Number: K124008

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