Zimmer Dental

1900 Aston Avenue
Carlsbad, CA 92008
760.929.4300 (ph)
760.431.7811 (fax)

510k No.: K113092

Page No.: A.5

JAN 23 2012

zimmer dental

Traditional 510(k)
PRE-MARKET NOTIFICATION 510(k)

510(k) SUMMARY (21CFR807.92(a))

1. Submitter's Information:

Name: Zimmer Dental Inc.

Address: 1900 Aston Ave.
Carlsbad, CA 92008

Phone: 760-929-4300

Contact: Jeremy Markovich

Date Prepared: October 17, 2011

2. New Device(s):

New Device No. 1
Trade Name: Zimmer® Contour Provisional Coping
Regulation Number: 872.3630
Classification Code: NHA
Device Classification Name: Endosseous Dental Implant Abutment

New Device No. 2
Trade Name: Zimmer® Short Provisional Coping
Regulation Number: 872.3630
Classification Code: NHA
Device Classification Name: Endosseous Dental Implant Abutment

3. Predicate Device(s):

Predicate Device No. 1
Trade Name: Zimmer® Contour Provisional Coping
510(k) Number: K061043
Regulation Number: 872.3630
Classification Code: NHA
Device Classification Name: Endosseous Dental Implant Abutment

Predicate Device No. 2
Trade Name: Zimmer® Short Provisional Coping
510(k) Number: K090723
Regulation Number: 872.3630
Classification Code: NHA
Device Classification Name: Endosseous Dental Implant Abutment

Predicate Device No. 3
Trade Name: Zimmer® Plastic Temporary Abutment
510(k) Number: K092377
Regulation Number: 872.3630
Classification Code: NHA
Device Classification Name: Endosseous Dental Implant Abutment

Predicate Device No. 4
Trade Name: Zimmer® Contour Healing Cap
510(k) Number: K061043
Regulation Number: 872.3630
Classification Code: NHA
Device Classification Name: Endosseous Dental Implant Abutment

Predicate Device No. 5
Trade Name: Zimmer® Short Healing Cap
510(k) Number: K090723
Regulation Number: 872.3630
Classification Code: NHA
Device Classification Name: Endosseous Dental Implant Abutment

4. Device Description:

The Contour Provisional Coping is a smooth plastic cap that fits passively over the cone of a Hex-Lock Contour Abutment or a Zimmer One-Piece Implant and mates with the margin of the abutment or implant abutment section. Each passive fit cap is affixed to the abutment/implant cone with appropriate dental adhesive material selected by the clinician.

The Short Provisional Coping is a tan, textured, plastic cap that fits passively over the cone of a Hex-Lock® Short Abutment and mates with the margin of the abutment.

5. Indication for Use:

The *Zimmer* Contour Provisional Coping is for use with a *Hex-Lock* Contour Abutment or a *Zimmer* One-Piece Implant to prevent irritation of soft tissue due to rubbing against the restorative area of the abutment or

implant, to prevent material from lodging in any undercuts or openings, and for fabricating a cement-retained provisional restoration. Use of the provisional coping is not to exceed 180 days.

The Short Provisional Coping is for use with a Short Hex-Lock Abutment to prevent irritation of soft tissue due to rubbing against the restorative area of the abutment or implant, to prevent material from lodging in any undercuts or openings, and for fabricating a cement-retained provisional restoration. Use of the provisional coping is not to exceed 180 days.

6. Device Comparison:

Zimmer Dental Inc. believes the Zimmer® Contour Provisional Coping and *Zimmer®* Short Provisional Coping to be substantially equivalent to their respective predicates as listed below. The modified devices are not subject to geometry modification and will be manufactured using the same process. The modified devices are equivalent in intended use, design, and materials. PEEK (polyether ether ketone) material demonstrates an improvement in functional performance compared to Ultem and PMMA. The modifications affect product labeling; however, these changes do not bring up new concerns regarding safety and efficacy and no new risks have been identified.

7. Technological Characteristics

Feature:	**New Device 1:** Contour Provisional Coping	**Predicate No. 1:** Contour Provisional Coping	**Predicate No. 2:** Zimmer Plastic Temporary Abutment	**Predicate No. 3:** Zimmer Contour Healing Cap
Material	PEEK (polyether ether ketone)	Ultem 1010-1101 (polyetherimide)	PEEK (polyether ether ketone)	PMMA Acrylic CP-1000-IG
Fit	Mates uniquely with shape of Contour abutment.	Mates uniquely with shape of Contour abutment.	Hexagon connection	Mates uniquely with shape of Contour abutment.
Design Feature	Has indexing / anti rotation feature	Has indexing / anti rotation feature	Straight or angled, collar heights in 1 or 4mm. Grooves for retention, defined margin	Has indexing / anti rotation feature
Feature:	**New Device 2:** Short Provisional Coping	**Predicate No. 1:** Short Provisional Coping	**Predicate No. 2:** Zimmer Plastic Temporary Abutment	**Predicate No. 3:** Short Healing Cap
Material	PEEK (polyether ether ketone)	Ultem 1010-1101 (polyetherimide)	PEEK (polyether ether ketone)	PMMA Acrylic CP-1000-IG
Fit	Mates uniquely with shape of short abutment.	Mates uniquely with shape of short abutment.	Hexagon connection	Mates uniquely with shape of Short abutment.

Design Feature	Has indexing / anti rotation feature	Has indexing / anti rotation feature	Straight or angled, collar heights in 1 or 4mm. Grooves for retention, defined margin	Has indexing / anti rotation feature

8. Non-Clinical Testing:

Non-clinical test data was not used to support the decision of safety and effectiveness. Clinical literature and material mechanical prosperities indicated that the device is strong enough to withstand the anticipated forces and demonstrated improvements over the predicate devices.

9. Clinical Testing

No clinical testing was performed. Non-clinical testing was used to support the decision of safety and effectiveness.

10. Conclusion

Based on our analysis, the device is substantially equivalent to the predicates and it is considered that the new device is as safe and effective for its intended use and performs as well or better than the predicate device(s).

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. Jeremy Markovich
Regulatory Affairs
Zimmer Dental Incorporated
1900 Aston Avenue
Carlsbad, California 92008

JAN 23 2012

Re: K113092
Trade/Device Name: Zimmer® Contour Provisional Coping
Zimmer® Short Provisional Coping
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: January 11, 2012
Received: January 17, 2012

Dear Mr. Markovich:

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

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

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

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

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

Sincerely yours,

for

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

Enclosure

zimmer dental

510k No.: _____
Page No.: A4-1

Zimmer® Contour Provisional Coping
Zimmer® Short Provisional Coping

Indications for Use

510(k) Number (if known): _____

Device Name: *Zimmer® Contour Provisional Coping*
Zimmer® Short Provisional Coping

Indications For Use:

The *Zimmer* Contour Provisional Coping is for use with a *Hex-Lock* Contour Abutment or a *Zimmer* One-Piece Implant to prevent irritation of soft tissue due to rubbing against the restorative area of the abutment or implant, to prevent material from lodging in any undercuts or openings, and for fabricating a cement-retained provisional restoration. Use of the provisional coping is not to exceed 180 days.

The Short Provisional Coping is for use with a Short Hex-Lock Abutment to prevent irritation of soft tissue due to rubbing against the restorative area of the abutment or implant, to prevent material from lodging in any undercuts or openings, and for fabricating a cement-retained provisional restoration. Use of the provisional coping is not to exceed 180 days.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K113090