K082523

Section 6: 510(k) Summary

SEP 2 6 2008

Applicant/ Manufacturer: Satu Komulainen
Osstell AB
Gamlestadsvagen 3 B
415 02 Goteborg
Sweden

Establishment Registration: 3004070020

US Contact: Cherita James
M Squared Associates, Inc.
901 King Street, Suite 200
Alexandria, VA 22314
Ph: 703-562-9800 Ext 257
Fax: 703-562-9797
E-mail: CJames@MSquaredAssociates.com

Date submitted: September 2, 2008

Proprietary Name: Osstell® ISQ Implant Stability Meter

Common Name: Dental implant stability analyzer

Classification Status: Class I

Product Codes: EKX - handpiece, direct drive, ac-powered

Predicate Device: Osstell Mentor Resonance Frequency Analyzer (K033689)

Device Description:

The Osstell® ISQ Implant Stability Meter is an updated version of the Osstell Mentor (K033689). The system is designed to measure dental implant stability in the oral cavity and craniofacial region. Similar to K033689, the Osstell ISQ is a portable, handheld instrument that involves the use of the noninvasive technique, Resonance Frequency Analysis. The system involves the use of a SmartPeg (aluminum rod) attached to the dental implant by means of a screw. The SmartPeg is excited by a magnetic pulse from the measurement probe on the handheld instrument. The resonance frequency, which is the measure of implant stability, is calculated from the response signal. Results are displayed as the Implant Stability

Quotient (ISQ). The ISQ is a measurement of the stability of the implant and is derived from the resonance frequency value obtained from the SmartPeg.

Indication for Use:

The Osstell ISQ is indicated for use in measuring the stability of implants in the oral cavity and craniofacial region. The Osstell ISQ can add important information to the evaluation of implant stability and can be used as part of an overall treatment evaluation program. The final implant treatment decisions are the responsibility of the surgeon.

Summary of Technological Characteristics:

The modifications to the Osstell Mentor since its previous clearance in K033689 include change to the circuit boards, integration of the docking station, and the software. These minor differences do not affect the safety or performance of the device and do not change the intended use of the Osstell ISQ.

Summary of Nonclinical Testing:

Based on the Risk Analysis, the verification and validation tests that were performed and the acceptance criteria applied for each are listed in Section 10. The Osstell ISQ was subject to the same preclinical requirements as the predicate device. Performance testing was conducted to confirm compliance to design specifications; all functions were verified to operate as designed.

Substantial Equivalence Discussion:

The change to the circuit boards, integration of the docking station, and the software of the Osstell ISQ do not change the intended use nor do they affect the safety and effectiveness as compared to the Osstell Mentor previously cleared in K033689.

Conclusion:

The modified Osstell ISQ has the following similarities to the Osstell Mentor previously cleared in K033689:

- has the same indicated use,
- uses the same operating principle,

- incorporates the same basic device design and physical properties,
- incorporates the same materials.

Therefore the modification to the Osstell ISQ can be found substantially equivalent to the Osstell Mentor cleared in K033689.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 17 2009

Osstell AB
c/o Ms. Cherita James
Regulatory Consultant
M Squared Associates, Incorporated
901 King Street, Suite 200
Alexandria, Virginia 22314

Re: K082523
Trade/Device Name: Osstell® ISQ
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EKX
Dated: September 2, 2008
Received: September 2, 2008

Dear Ms. James:

This letter corrects our substantially equivalent letter of September 2, 2008

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 (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

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

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

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-3773 http://www.fda.gov/cdrh/organiz.html#OCfor OC organization structure). Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K082523

Section 5: Indications for Use Statement

510(k) Number (if known): ____

Device Name: Osstell® ISQ

Indications For Use: Osstell® ISQ Implant Stability Meter is indicated for use in measuring the stability of implants in the oral cavity and craniofacial region.

Prescription Use ___X___ AND/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 NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K082523

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