DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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February 19, 2015

Osstell AB
Ms. Karin Breding
QA & RA Manager
Stampgatan 14
411 01 Goteborg
SWEDEN

Re: K142358
Trade/Device Name: Osstell IDx
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental handpiece and accessories
Regulatory Class: Class I
Product Code: EKX
Dated: January 29, 2015
Received: February 2, 2015

Dear Ms. Breding:

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,

Tina Kiang -S

for Erin 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

Section 5: Indications for Use Statement

510(k) Number (if known): K142358

Device Name: Osstell IDx

Indications For Use: The Osstell IDx is indicated for use in measuring the stability of implants in the oral cavity and maxillofacial 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)

Section 6: 510(k) Summary

Applicant/ Manufacturer:

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Establishment Registration Number: 3004070020

Date submitted:	2014-08-22
Proprietary Name:	Osstell IDx
Common Name:	Dental implant stability analyzer
Classification Status:	Class I
Product Codes:	EKX - handpiece, direct drive, ac-powered
Predicate Device:	Osstell ISQ (K082523)
Regulation Number:	21 CFR 872.4200
Regulation Name:	Dental handpiece and accessories

Device Description:

The Osstell IDx is a modification of the Osstell ISQ (K082523). The system is designed to measure implant stability in the oral cavity and maxillofacial region. Similar to K082523, the Osstell IDx is a portable, handheld/tabletop 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 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. The Osstell IDx 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.

Indication for Use:

The Osstell IDx is indicated for use in measuring the stability of implants in the oral cavity and maxillofacial region.

Summary of Technological Characteristics:

The modifications to the Osstell ISQ since its previous clearance in K082523 include the following changes:

- Replacing the existing display with a touch screen
- New material is added
- Updated user interface
- Cloud connection

These differences do not affect the safety or performance of the device and do not change the intended use of the Osstell IDx. These changes were implemented to improve the customer need, which is done with an improved user interface. The new material in the probe improves the grip ability. The cloud connection automatically enables the user to install the latest firmware updates.

Summary of Nonclinical Testing:

Based on the Risk Analysis, the verification and validation tests that were performed and the acceptance criteria applied for each were found to pass. The Osstell IDx was subjected to the same preclinical requirements and testing as the predicate device. Performance testing was conducted to confirm compliance to the design specifications; all functions were verified to operate as designed.

A Nonclinical evaluation has been performed where the Osstell IDx has been compared to the predicate device Osstell ISQ. Two different evaluations have been performed.

Test Method: 30229-07 SmartPeg development verification tests
Osstell Instrument nr 024
IDx instrument. SW version p2f. Hardware version Circuit board: C

Non-clinical evaluation method	Acceptance Criteria	Results
ISQ correlation evaluation	The average difference could be up to +/-5 ISQ.	Approved. The average difference was -1 ISQ and 3,17 ISQ
Torque correlation evaluation.	The average variance due to tightening torque is checked so that it stays within 3 ISQ between 4 and 6 Ncm.	Approved. The highest variance due to tightening torque were measured to 1,33 ISQ. Most of the measured variances were 0 or below 1 ISQ:
Nonclinical Biocopmatibility evaluation of the new probe material.	Approved Biocopmatibility evaluation according to ISO 10993.	Mediprene 500M has passed cytotoxicity test according to ISO 10993-5 and biocompatibility tests according to USP Class VI. Due to very low degree of skin contact and that the ingoing materials are well knowned. The individual materials have passed the biocompatibility evaluation and the combination into a steam autoclavable

		product is judged not to change the risk spectrum. Based on the low degree and duration of skin contact, the biocompatibility tests performed is the biocompatibility evaluation approved for the IDx Probe.

Clinical Studies:

Clinical data was not required to support the changes to the Osstell IDx.

Substantial Equivalence Discussion:

The changes to the display, user interface, electronics and material of the Osstell IDx do not change the intended use nor do they affect the safety and effectiveness as compared to the Osstell ISQ previously cleared in K082523.

	Osstell IDx	Predicate Device: Osstell ISQ K082523
Device name	Osstell IDx	Osstell® ISQ
Company name	Osstell AB	Osstell AB (formerly Integration Diagnostics)
Product Code/Class	EKX/Class I	Same
Regulation Number	872.4200	Same
Classification name	Handpiece, Direct Drive, AC-Powered	Same
Intended Use	Dental implant stability analyzer	Same
Indication for use	The Osstell IDx is indicated for use in measuring the stability of implants in the oral cavity and maxillofacial region.	The Osstell IDx is indicated for use in measuring the stability of implants in the oral cavity and craniofacial region.
Description	Portable, handheld/tabletop, or freestanding instrument indicated for use in measuring the stability of implants in	Portable, handheld, or freestanding instrument indicated for use in measuring the stability of implants in the oral cavity

	Osstell IDx	Predicate Device: Osstell ISQ K082523
	the oral cavity and maxillofacial region.	and craniofacial region.
Operation of System	The Osstell IDx measures the frequency response from Smartpeg that is directly attached to the implant or abutment. The system includes the following components: Instrument, Smartpeg/Measurement Probe, The technique involves a SmartPeg (10 mm x 3 mm) that is attached to the implant or abutment. The SmartPeg is excited over a range of frequencies (1 kHz to 10 kHz) and the resonance frequency is measured with the Osstell IDx instrument and software. The resonance frequency is determined by the stiffness of the implant system. The Osstell IDx presents the resonance frequency as an Implant Stability Quotient (ISQ) value (scaled 0-100). The ISQ value is proportional to the stability of the implant. (In general, a rise in ISQ values from one measurement time to the next indicates a progression towards stability and a lower ISQ value may indicate a loss in stability and perhaps, implant failure.)	The Osstell ISQ measures the frequency response from Smartpeg that is directly attached to the implant or abutment. The system includes the following components: Instrument, Smartpeg/Measurement Probe, and PC Data Manager Software The technique involves a SmartPeg (10 mm x 3 mm) that is attached to the implant or abutment. The SmartPeg is excited over a range of frequencies (1 kHz to 10 kHz) and the resonance frequency is measured with Osstell ISQ instrument and software. The resonance frequency is determined by the stiffness of the implant system. The Osstell ISQ presents the resonance frequency as an Implant Stability Quotient (ISQ) value (scaled 0-100). The ISQ value is proportional to the stability of the implant. (In general, a rise in ISQ values from one measurement time to the next indicates a progression towards stability and a lower ISQ value may indicate a loss in stability and perhaps, implant failure.)
System Components-	**Instrument** The Instrument is a portable , handheld/tabletop instrument with a touch display. The unit operates from a rechargeable power source offering 1 hour of continuous use between charges. The operator instructions enables patients recording and monitoring implant progress. The size of the touch screen is 154 x 94 mm. Firmware can be updated either through USB connector or cloud connection. **Measurement Probe** The Measurement Probe is connected to the instrument via the probe cable and is held close to the Smartpeg. The measurement probe sends the excitation signal to the coils in the probe, and also detects the response signal from the detection coil in the probe. The microcontroller in the instrument calculates the frequency of the response	**Instrument** The Instrument is a compact unit with built-in graphical display. The unit operates from a rechargeable power source offering over 6 hours of continuous use between charges. The size of the LCD display is 69 *37 mm The instrument can be connected to a PC via the USB cable and the measurement data can be transferred to the optional ISQ Data Manager Software. **Measurement Probe** The Measurement Probe is connected to the instrument via the probe cable and is held close to the Smartpeg. The measurement probe sends the excitation signal to the coil in the probe, and also detects the response signal from the second coil in the probe. The microcontroller in the instrument calculates the frequency of the response signal, and presents it on the display as a

	Osstell IDx	Predicate Device: Osstell ISQ K082523
	signal, and presents it on the display as a number, the Implant Stability Index (ISQ). The measurement probe has fixed cable. **Smartpeg** The stability of the implant is reflected by the resonance frequency of a "Smartpeg" attached to the implant. The Smartpeg is a small aluminum rod, approximately 3 mm in diameter and 10 mm long, with a magnet permanently attached to its top. The Smartpeg is screwed onto the implant. The Smartpeg magnet is excited by a small magnetic pulse generated by a coil in the measurement probe. The Smartpeg vibrates freely at its resonance frequency for some milliseconds. Since the magnet attached to its top is vibrating together with the Smartpeg, the vibration (the "ringing") can be picked up by a second coil in the measurement probe. **PC Data Manager Software** The system has no PC Data Manager Software.	number, the Implant Stability Index (ISQ). The measurement probe has fixed cable. **Smartpeg** Same **PC Data Manager Software** The Osstell ISQ Data Manager is a Windows 2000/NT/XP/Vista based software enabling storage, viewing and printing of patient data. The Software is an optional accessory to the Osstell ISQ and is not integral to the functioning of the device. Patients may be tracked and implant progress monitored after transfer of data from the instrument to a PC. The data is transferred from the instrument to a PC. The data is transferred directly from the Osstell ISQ instrument to a PC via the USB cable.
Power, Weight and Size	Rated Power: 12VA Instrument Size: 210 mm X 165 mm X 55 mm Instrument Weight: 0.750kg Accuracy: ±2ISQ units	Rated Power: 5VA Instrument Size: 190 x 120 x 45 mm Instrument Weight: 0.4 kg Accuracy: ±2 ISQ units
Instrument materials	ABS Plastic	Same
Probe materials	Probe: Thermoplastic elastomer, medical grade USP class VI	Probe: PPSU , stainless steel Cable: silicone

	Osstell IDx	Predicate Device: Osstell ISQ K082523
	Cable: Silicone Cable connector: Natural polyestersulfone	Cable connector: Natural polyestersulfone
Device Display	Touch display – 155 x 94 mm	LCD – 64x 32-mm
Software Testing and Validation	Software verification and validation performed.	Same
Mechanical/ Electrical safety /Standards	The Osstell IDx was designed and constructed with applicable standards	Same
Sterile components/ methods	Probe with cable /autoclave SmartPeg /single patient use	Same
Contraindication	None	None
Location of Use	Dental practice or operating room.	Same
User	Professional clinicians	Same

Conclusion:

Based on the results of the tests performed in the nonclinical testing and biocompatibility performed, the product is approved for its intended use in terms of Non clinical evaluation.

The modified Osstell IDx has the following similarities to the Osstell ISQ previously cleared in K082523:

- has the same indications for use,
- uses the same operating principle,
- has no change in single use components

Therefore the modification to the Osstell IDx can be found substantially equivalent to the Osstell ISQ cleared in K082523.