August 22, 2019

Osstell AB
% Cherita James
Regulatory Consultant
M Squared Associates, Inc
575 8th Ave Suite 1212
New York, NY 10018

Re: K181888
Trade/Device Name: Osstell Beacon
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: Class I
Product Code: EKX
Dated: July 23, 2019
Received: July 24, 2019

Dear Cherita James:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Srinivas Nandkumar, Ph.D.
Acting Assistant Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K181888

Device Name
Osstell Beacon

Indications for Use *(Describe)*
Osstell Beacon is indicated for use in measuring the stability of implants in the oral cavity and maxillofacial region.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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# 510(k) Summary

The following information is provided as required by 21 CFR § 807.87 for the Osstell Beacon 510(k) premarket notification. In response to the Safe Medical Devices Act of 1990, the following is a summary of the information upon which the substantial equivalence determination is based.

**Sponsor:** **Osstell AB**
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**Contact:** **Cherita James**
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**Revision Date:** August 19, 2019

**Proprietary Name:** Osstell Beacon

**Common Name**: Dental implant stability analyzer

**Regulatory Class:** Class 1

**Regulation:** 872.4200

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

**Predicate Device:** Osstell ISQ (K082523)-Primary

Tellos ISQ Buddy (K143445) and Implantmed SI-1015 (K161957)- Reference

**Device Description:**

The Osstell Beacon 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 Beacon 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 implant by means of a screw. The Smartpeg is excited by a magnetic pulse from the measurement tip 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.

**Intended Use:**

Osstell Beacon is intended for use as a Dental Implant Stability Analyzer

**Indications for Use:**

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

**Summary of the Technological Characteristics:**

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

- Enclosure design is smaller to be fully handheld. The measurement probe with tip is integrated into the enclosure and referred to as the measurement tip
- Not possible to sterilize (autoclave). The device must be used with a transparent barrier sleeve. Commercially available transparent, barrier sleeves are recommended in the Instructions for Use.
- Different plastic material used in the enclosure (all being food grade compliant, 21 CFR §181.32 and 21 CFR §177.1580)
- Updated user interface to make the measurement procedure even more easy and intuitive
- The device cannot measure while charging
- Bluetooth data communication

These differences do not affect the substantial equivalence or performance of the device and do not change the intended use of the Osstell Beacon.

**Summary of the Nonclinical Testing:**

Based on the Risk Analysis, the verification and validation testing confirms the Beacon performs as intended. The Osstell Beacon was subjected to the same preclinical requirements and testing as the primary predicate device.

Though the recommendation require use of a transparent barrier sleeve, due to material changes, the device was evaluated in accordance with ISO 10993-1.

Additionally, cleaning and disinfection recommendations were validated in the event the Osstell Beacon should become contaminated due to a damaged barrier sleeve.

Performance testing was conducted to confirm compliance to the design specifications.

Osstell has provided information to support compliance of Beacon with applicable portions of the following standards and FDA Guidance documents:

- FDA Dental Handpieces – Premarket Notification [510(k)] Submissions, 2007
- FDA Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, 2015
- FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, 2005
- ISO 10993-1
- ISO 10993-5
- AAMI TIR12:2010
- AAMI TIR30:2011
- ASTM E1837-96 (2014)
- ISO 17665-1
- ISO 17664
- IEC 60601-1, Ed 3 2005
- IEC 60601-1-2:2015
- IEC 62133

**Substantial Equivalence Discussion:**

The changes to the enclosure, no longer capable to withstand sterilization and instead use of barrier sleeves, electronics, user interface and communication do not change the intended use, nor do they affect the substantial equivalence as compared to the Osstell ISQ previously cleared in

K082523.

| | Osstell Beacon | Predicate Device: Osstell ISQ | Reference Device: Tellos ISQ Buddy | Reference Device: Implantmed SI-1015 incl. Accessories | Substantial Equivalence |
|---|---|---|---|---|---|
| **K#** | To be assigned | K082523 | K143445 | K161957 | - |
| **Device name** | Osstell Beacon | Osstell® ISQ | Tellos ISQ Buddy (marketed as Penquin RFD) | Implantmed SI-1015 incl. Accessories | - |
| **Company name** | Osstell AB | Osstell AB | Tellos Medical AB | W & H DENTALWERK BÜRMOOS GMBH | - |
| **Classification** | Class I | Same | Same | Same | - |
| **Regulation Number** | 872.4200 | Same | Same | Same | - |
| **Classification name** | Handpiece, Direct Drive, AC-powered | Same | Same | Same | - |
| **Intended Use** | Dental implant stability analyzer | Same | Same | Mechanical drive for dental instruments with ISQ module used to measure implant stability. | Same |
| **Indication for use** | Indicated for use in measuring the stability of implants in the oral cavity and maxillofacial region. | Indicated for use in measuring the stability of implants in the oral cavity and craniofacial region. | Indicated for use in measuring the stability of dental implants in the oral cavity and the maxillofacial region. | Mechanical drive unit with coolant supply for transmission instruments with ISO 3964 (DIN13940) compatible coupling system, for use in dental surgery, implantology and maxillofacial surgery (CMF) for treatment of dental hard tissue. Includes ISQ module used to measure implant stability. | Subject, primary predicate, and K143445 reference device are identical.<br><br>K161957 reference device used for Bluetooth technology has a different indication, however the comparison is only for Bluetooth technology and does not have specific indications for this technology |
| **Description** | Portable, handheld battery driven instrument indicated for use in measuring the stability of implants in the oral cavity and maxillofacial region. | Portable, handheld, or freestanding instrument indicated for use in measuring the stability of implants in the oral cavity and craniofacial region. | Hand-held, battery-driven device for measuring the relative stability of a dental implant. | - the control unit,<br>- a motor with cable with or without light (EM-19 LC/EM-19),<br>- a wireless or wired foot control (S-NW or S-N2),<br>- the Osstell Module (SI-SQ)<br>- and as an attachment the surgical handpieces | All are portable handheld devices, the change in configuration compared to ISQ which incorporates the device controls and displays into a single handheld does not impact the substantial equivalence of |

| | Osstell Beacon | Predicate Device: Osstell ISQ | Reference Device: Tellos ISQ Buddy | Reference Device: Implantmed SI-1015 incl. Accessories | Substantial Equivalence |
|---|---|---|---|---|---|
| | | | | - (WS-56 L, WS-75 L, WS-91 L, WS-92 L and S-11 L).<br>The user can select five different programs. Switching between<br>these programs is performed by foot control or via touch display. | the device.<br><br>ISQ Buddy is also portable, handheld and Implantmed uses a wireless foot pedal via Bluetooth technology.<br><br>Verification of the Beacon confirms it performs as intended. |
| **Operation of System** | Measures the frequency response from Smartpeg that is directly attached to the implant or abutment. The system includes the following components: Instrument, Osstell Smartpeg, Osstell SmartPeg Mount, Osstell USB cable, Osstell TestPeg<br><br>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 Beacon instrument and software. The resonance frequency is determined by | Measures the frequency response from Smartpeg that is directly attached to the implant or abutment. The system includes the following components: Instrument, Osstell SmartPeg, Osstell Measurement Probe, Osstell SmartPeg Mount, Osstell USB Cable, Osstell TestPeg<br><br>Same technique is used in operating the system as the Osstell Beacon device. | A microcontroller sends electric pulses to a coil in the instrument tip. As a consequence, magnetic pulses are emitted that affect the pin connected to the implant. The pin then starts to vibrate with its resonance frequency. Vibration creates an alternating magnetic field which is being picked up by another coil in the instrument tip. The electrical signal from the receiving coil is analyzed and the frequency is determined. The Frequency is presented on the display as an "ISQ- value"<br><br>Resonance frequency of the ISQ peg as an ISQ number, 1-100. The ISQ | Referenced specific to wireless foot pedal; however, devices include a ISQ module used to measure implant stability. | There is no difference in the system operation between the subject device and K082523 or K143445. |

| | Osstell Beacon | Predicate Device: Osstell ISQ | Reference Device: Tellos ISQ Buddy | Reference Device: Implantmed SI-1015 incl. Accessories | Substantial Equivalence |
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| | the stiffness of the implant system. The Osstell Beacon 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.<br><br>(In general, an increase in ISQ value from one measurement time to the next indicates a progression towards higher stability and a lower ISQ value may indicate a loss in stability and perhaps, implant failure.)<br>Bluetooth functionality for device production purposes only | | number is calculated from the resonance frequency. | | |
| **System Components** | **Instrument**<br>A portable, handheld instrument with 2 built-in graphical displays. The unit operates from a rechargeable power source offering more than 400 ISQ measurements between charges.<br>The size of the displays is 14 x 11 mm.<br><br>**Measurement tip** | **Instrument**<br>A portable, handheld, or freestanding instrument with built-in graphical display. The unit operates from a rechargeable power source offering over 6 hours of continuous use between charges.<br>The size of the LCD display is 69 x 37 mm<br>The instrument can be connected to a PC via the USB cable and the measurement data | Tellos ISQ Buddy instrument, ISQ Peg, ISQ Peg Driver and instrument charger.<br><br>Tellos ISQ Buddy has two LED-displays; one on each side of the instrument for easy reading.<br><br>Tellos ISQ Buddy uses the Osstell SmartPegs, or corresponding Tellos pins, | - the control unit,<br>- a motor with cable with or without light (EM-19 LC/EM-19),<br>- **a wireless** or wired foot control (S-NW or S-N2),<br>- the Osstell Module (SI-SQ)<br>- and as an attachment the surgical handpieces<br>- (WS-56 L, WS-75 L, WS-91 L, WS-92 L and S-11 L). | The change in configuration and components from the ISQ which incorporates the device controls and displays into a single handheld for the Beacon does not impact the substantial equivalence of the device.<br><br>Tellos ISQ Buddy also is portable, handheld device with LED displays, and employs "SmartPegs or |

| | Osstell Beacon | Predicate Device: Osstell ISQ | Reference Device: Tellos ISQ Buddy | Reference Device: Implantmed SI-1015 incl. Accessories | Substantial Equivalence |
|---|---|---|---|---|---|
| | The measurement tip is held close to the Smartpeg. The measurement electronics sends the excitation signal to the coils in the tip, and also detects the response signal from the detection coil in the tip. The microcontroller in the instrument calculates the frequency of the response signal, and presents it on the display as a number, the Implant Stability Quotient (ISQ).<br><br>**Smartpeg**<br>The stability of the implant is reflected by the resonance frequency of the "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 | can be transferred to the optional ISQ Data Manager Software.<br><br>**Measurement Probe with tip**<br>The Measurement Probe is connected to the instrument via the probe cable and is held close to the Smartpeg. The measurement electronics sends the excitation signal to the coil in the probe with tip, and also detects the response signal from the detection coil in the probe with tip. The microcontroller in the instrument calculates the frequency of the response signal, and presents it on the display as a number, the Implant Stability Index (ISQ). The measurement probe has fixed cable.<br><br>**Smartpeg**<br>Same- No change to the Smartpeg<br><br>**Data communication**<br>The Osstell ISQ Data Manager is a Windows 2000/NT/XP/Vista based software enabling storage, viewing and printing of measured data. The Software is an optional accessory to the Osstell ISQ and is not integral | "ISQ Pegs" from titanium. | | ISQ Pegs. The Implantmed SI device, is referenced specific to wireless foot pedal, which also utilizes Bluetooth software functionality..<br><br>Verification of the Beacon confirms it performs as intended. |

| | Osstell Beacon | Predicate Device: Osstell ISQ | Reference Device: Tellos ISQ Buddy | Reference Device: Implantmed SI-1015 incl. Accessories | Substantial Equivalence |
|---|---|---|---|---|---|
| | measurement tip. The Smartpeg vibrates freely at the resonance frequency for some milliseconds. By means of the magnet, the vibration (the "ringing") can be picked up by a second coil in the instrument tip.<br><br>**Bluetooth communication** The Osstell Beacon contains a built in Bluetooth 4.0 low energy module device for production purposes only. | to the clinical functioning of the device. | | | |
| **Power, Weight and Size** | Power source: Lithium-ion cell (3.7V, 0.8 Ah)<br>Instrument Size: 210 x 35 x 25 mm<br>Instrument Weight: 0.07kg<br>Accuracy: ±2 ISQ units | Power source: Lithium-ion cell (3.7V, 2.2 Ah)<br>Instrument Size: 190 x 120 x 45 mm<br>Instrument Weight: 0.4 kg<br>Accuracy: ±2 ISQ units | Re-chargeable NiMh-batteries | Main dimension: 154x202x210<br>Features:<br>4 buttons for pump on/off<br>Forward/reverse<br>Change programs<br>Motor control (on/off and variable)<br>Power supply: wireless<br>via 3xAA batteries | Minor differences in power, weight and size do not affect the performance of the Beacon when compared to the Osstell ISQ.<br><br>ISQ Buddy is also portable, handheld. The Implantmed device is only referenced for its use of a Bluetooth wireless foot pedal. |
| **Instrument materials** | ABS and PC Plastic | ABS and PC plastic | PC/ABS | N/A: Only referenced specific to wireless foot pedal. | No change. |
| **Probe TIP materials** | ABS Plastic | Probe: PPSU, stainless steel<br>Cable: silicone<br>Cable connector: Natural polyestersulfone | PEEK | N/A: Only referenced specific to wireless foot pedal. | Materials do not effect the device performance. Beacon performs as intended. |

| | Osstell Beacon | Predicate Device: Osstell ISQ | Reference Device: Tellos ISQ Buddy | Reference Device: Implantmed SI-1015 incl. Accessories | Substantial Equivalence |
|---|---|---|---|---|---|
| **Device Display** | 2 pcs OLED – displays 14 x 11 mm | LCD – 69x 37-mm | LED | N/A: Only referenced specific to wireless foot pedal. | Beacon display meets the requirements of the end user and is same as ISQ Buddy. |
| **Software Testing and Validation** | System and software verification and validation performed. | Same | Unknown | For the new wireless foot control (S-NW) software verification/validation of the functions of the foot control was conducted according to IEC 62304:2006. | No change in software required for the configuration changes. |
| **Mechanical/ Electrical safety /Standards** | The Osstell Beacon is designed and manufactured with applicable standards:<br>IEC 60601-1<br>IEC 60601-1-2<br>IEC 62133 | Same | Same | EMC testing was performed to evaluate the risk of communication loss according to IEC 60601-1-2:2007 and Electrical Safety Tests done according to IEC 60601-1-1:2005. | All devices substantially equivalent for intended use |
| **Sterile components/ methods** | Instrument not sterile and cannot be autoclaved/Must use a transparent, barrier sleeve<br><br>SmartPeg /single patient use | Probe with cable /autoclave<br><br>SmartPeg /single patient use | Instrument not sterile and cannot be autoclaved/Must use a transparent, barrier sleeve<br><br>ISQ Peg/re-sterilized | Surgical Handpieces | Transparent barrier use in the Beacon ensure no cross contamination between patients. |
| **Instrument Cleaning and Disinfection** | Intended for use with transparent barrier ensure no cross contamination between patients.<br><br>Validated cleaning and HLD in the event of barrier damage. | Patient contacting probe sterilizable | Intended for use with transparent barrier ensure no cross contamination between patients. | Cleaning: rinse under demineralized water (< 38°C/100°F) with aid of brush<br><br>Disinfection: wiping disinfection using disinfectant cloths<br><br>Sterilization: Dynamic-air-removal Sterilizers or Gravity displacement sterilizers | Both Tellos Buddy ISQ and Beacon employ sleeves to protect against contamination. Tellos User manual does not define validated cleaning and disinfection steps. |
| **Contraindication** | Osstell Beacon is contraindicated for implant systems to which the SmartPeg could | Same | Unknown | Unknown | No change in contraindications. |

| | Osstell Beacon | Predicate Device: Osstell ISQ | Reference Device: Tellos ISQ Buddy | Reference Device: Implantmed SI-1015 incl. Accessories | Substantial Equivalence |
|---|---|---|---|---|---|
| | not be attached for mechanical incompatibility reasons. Osstell Beacon is contraindicated where it is not possible to attach the SmartPeg due to lack of space, or where it impinges on other artificial or anatomical structures. | | | | |
| **Location of Use** | Dental practice or operating room. | Dental practice or operating room. | Dental practice or operating room. | Dental practice or clinic | Same use environment. |
| **User** | Professional clinicians | Professional clinicians | Professional clinicians | Professional clinicians | Same intended user |

**Clinical Data:**

Clinical studies were not required to validate the modifications in the Osstell Beacon.

**Conclusion:**

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

- has the same intended and indicated use, to be used for the same professional clinicians and in the same environment
- it uses the same operating principle of utilizing Osstell RFA measurement technology, circuitry and ISQ software algorithm
- Biologically equivalent materials (food grade) in the instrument tip.
- it uses the same, single use, measurement pins, i.e. the Osstell SmartPegs

The modifications to the Osstell Beacon can therefore be found substantially equivalent to the Osstell ISQ cleared in K082523, as well as features of the Tellos ISQ Buddy (K143445) and

Implantmed SI-1015 (K161957.

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