Hiossen, Inc.
David Kim
RA Manager
85 Ben Fairless Dr.
Fairless Hills, Pennsylvania 19030

May 16, 2018

Re: K180527
Trade/Device Name: IS3
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: Class I
Product Code: EKX
Dated: February 28, 2018
Received: February 28, 2018

Dear David Kim:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*
K180527

Device Name
IS3

Indications for Use *(Describe)*
IS3 is indicated for use in measuring the stability of dental implants in the oral cavity and the 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

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date : Feb 26, 2018

1. Company and Correspondent making the submission

1) Submitter's Name :	HIOSSEN, Inc.
2) Address :	85 Ben Fairless Dr. Fairless Hills, PA 19030 USA
3) Telephone No.	888 678 0001
4) Contact :	Mr. David Kim

2. Device

Trade or (Proprietary) Name :	IS3
Common or usual name :	Dental implant stability analyzer
Accessories name :	Mult-Peg
Regulation number :	872.4200
Classification code :	EKX
Device class :	Class I

3. Predicate Device

Primary Predicate Device : Tellos ISQ Buddy (K143445)
Reference Predicate Device : Osstell ISQ (K082523)

4. Device Description :

4.1. Description : IS3 measurement system consists of:

IS3 Instrument Hand-held instrument

Multi Peg Driver	Driver to attach the ISQ peg to the implant
IS3 Charger	100-240 VAC to 5VDC charger for the instrument batteries
Multi Peg	Measurement pin to attach to the implant. Different pins are available to fit different implant types.

4.2. Basic principle and functionality

The IS3 instrument is a hand-held, battery-driven device for measuring the relative stability of a dental implant. A small pin "Multi peg" is attached to the dental implant by a screw-connection, with the Multi Peg Driver. The pin has a small magnet incorporated into its top. The instrument is held towards the Multi Peg, and sends short magnetic pulses that bring the pin into vibration. After a pulse has been sent, the instrument measures the vibration by sampling the signal from the alternating magnetic field that follows from the vibrating pin. The frequency of the signal is determined by the instrument and is presented as an "ISQvalue", 1 to 100, where a higher number means higher stability. The measurement takes about 1 second.

4.3. Technical detail

The instrument consists of a microcontroller and circuits to send the magnetic pulses, to receive the measurement signal, and to present the measurement value. A circuit for battery-charging is also included. Two 2-digit LED displays, one on each side of the instrument, show the measurement value and also communicate possible error codes and software id number at start-up. One operating key is used to turn the instrument on and off. The electronics are contained in a plastic body, which is sealed except for the back of the instrument which has a charging connector. The plastic body is made from PC/ABS plastic except for the tip, which is made from PEEK. No part of the instrument is intended to contact the patient; however, there can be unintentional contact with the tip of the instrument. The instrument is battery-driven and contains re-chargeable NiMh-batteries. The batteries can be charged during use, but it should not be attached while measuring due to the risk of power line interference making it impossible to measure. For safety, a charger complying with IEC 60601-1 is used.The charger connector is of a type that does not allow other chargers to be connected, thereby eliminating the risk of the wrong charger being used.

4.4. Material used

Instrument body: PC/ABS
Instrument tip: PEEK (USP VI)
Instrument seal : Silicone (USP VI)
Instrument key : Silicone (USP VI)
Multi Peg Driver: Stainless steel, ASTM F899
Multi Peg: Titanium grade 5, ASTM F136

5. Indication for Use

IS3 is indicated for use in measuring the stability of dental implants in the oral cavity and the maxillofacial region.

6. Comparison and differences to the Predicate Device

The instrument functions the same way as the predicate device regarding the measurement principle and technology used. There is no difference in between the subject device and primary predicate device. The differences with reference device are in the handling; The IS3(subject device) and Tellos(primary predicate device) are hand-held instruments while the Osstell ISQ(reference

predicate device) consists of two parts; the instrument and the measurement probe. The IS3(subject device) and Tellos(primary predicate device) have no memory to store the measurement values; the reference predicate device has a memory that stores the measurements and also has an inbuilt clock timer, and a computer connection for transferring measurement values. IS3 and Primary predicate device has no timer or computer connection. The lack of these features (memory, timer, data transfer) is not considered to be an inconvenience for the user. Instead, it decreases the risk of mixing up values with each other.

	Proposed device	**Primary Predicate devices**	**Reference Predicate device**
	IS3	Tellos ISQ Buddy (k143445)	Osstell ISQ (k082523)
Manufacturer	HIOSSEN, INC.	Tellos Medical AB	Osstell AB
Product Code /Class	EKX / Class I	EKX / Class I	EKX / Class I
Regulation Number	872.4200	872.4200	872.4200
Indication for Use	Same as primary predicate device.	The device is indicated for use in measuring the stability of implants in the oral cavity and the maxillofacial region.	The device is indicated for use in measuring the stability of implants in the oral cavity and craniofacial region.
Target Population	Same as primary predicate device.	Patients with one or more dental implants	Patients with one or more dental implants
Anatomical site	Same as primary predicate device.	Oral cavity or craniofacial region	Oral cavity or craniofacial region
Usage location	Same as primary predicate device.	Dentists office or hospital	Dentists office or hospital
Energy used/delivered	Same as primary predicate device.	No energy is intended to be delivered. A small amount of energy could reach the dental implant from the self-vibrating measurement pin.	No energy is intended to be delivered. A small amount of energy could reach the dental implant from the self-vibrating measurement pin.
Technology	Same as primary predicate 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	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 "ISQvalue"	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 "ISQvalue"
Measurement output	Same as primary predicate device.	It presents the resonance frequency of the ISQ peg as an ISQ number, 1-100. The ISQ number is calculated from the resonance frequency.	It presents the resonance frequency of the ISQ peg as an ISQ number, 1-100. The ISQ number is calculated from the resonance frequency.
Operation	Same as primary predicate device.	The operating key is pushed and the instrument is held towards the attached ISQ peg. The instrument then presents the ISQ value.	Any key is pushed and the measurement probe is held towards the attached SmartPeg. The instrument then presents the ISQ value.
System components	Same as primary predicate device.	Tellos ISQ Buddy instrument, ISQ Peg, ISQ Peg Driver and instrument charger.	Osstell ISQ instrument, measurement probe, SmartPeg and instrument charger.
Power, weight & size	Same as primary predicate device.	3VA, 0.1 Kg, 200 x 30 mm	8 VA, 0.4 Kg, 195 x 20 x 45 mm
Materials used	Same as primary predicate device.	Instrument; PC/ABS and PEEK. Gasket and operating key: Silicone ISQ Peg Driver: Stainless steel ISQ Peg: Titanium	Instrument: Not available Measurement probe: Not available SmartPeg driver: Not Available SmartPeg: Aluminum
Instrument memory	Same as primary predicate device.	Tellos ISQ Buddy has no data memory.The instrument displays the measurement value after the measurement. The memory is not a necessary feature and the absence of a memory decreases the risk of mixing up values between different implants during a patient session.	Osstell ISQ has a memory for storing measurement values.
Instrument setup-menu	Same as primary predicate device.	No setup-menu is needed for Tellos ISQ Buddy. The instrument has one operating key and no parameters to change.	Instrument has a setup-menu for various instrument parameters such as display contrast and computer connection.
Data transfer	Same as primary predicate device	Since Tellos ISQ Buddy has no memory,there are no data to transfer. This is not a necessary feature, and the absence of a data transfer function decreases	Osstell ISQ has a cable attachment to a PC computer, for transferring data.

		the risk of mixing up values between different implants during a patient session.	
Clock Timer	Same as primary predicate device	Since Tellos ISQ Buddy has no memory, there is no need for a clock timer.	Osstell ISQ has a built-in clock timer.
Number of operating keys	Same as primary predicate device	Tellos ISQ Buddy has one operating key, used for turning on and off the instrument. Since the instrument has no memory or setup-menu, not more than one key is needed. With one key,the instrument is more intuitive and easier to use, which leaves less room for user errors compared to the predicate device.	Osstell ISQ has 5 operating keys, for working the setup-menu and for navigating the instrument memory.
Display	Same as primary predicate device	Tellos ISQ Buddy has two LED-displays; one on each side of the instrument for easy reading.	Osstell ISQ has one LCD display on the instrument.
Measurement pins	Same as primary predicate device	Tellos ISQ Buddy uses the Osstell SmartPegs, or corresponding Tellos pins, “ISQ Pegs” from titanium.	Osstell ISQ uses disposable aluminum pins, “SmartPegs”.
Electrical safety	Same as primary predicate device	It is designed to the standard IEC 60601-1 Medical Electrical Equipment	Osstell ISQ is designed to the standard IEC 60601-1 Medical Electrical Equipment

7. Performance testing

The IS3 instrument brings a pin attached to a dental implant into vibration and then measures the resonance frequency of the vibrating pin. The resonance frequency is then presented as an “ISQ-value” 1-100. The primary predicate device does the same technological principle and the electronic, software since same circuits are used.

The IS3 instrument has been tested according to, and found to comply with the following:

- EMC standard IEC 60601-1-2
- Software validation according to FDA guidance for Software Contained in a Medical Device
- Sterilization validation according to ISO 17665-1 and ISO 17665-2
- Biocompatibility standard ISO 10993-1

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8. Substantial Equivalence Conclusion

The purpose of using the instrument is to measure the ISQ value (the relative stability) of the implant. The IS3 has the same indication for use, measurement output and technology as the primary predicate device.

The device description, software validation, performing testing, sterilization validation and biocompatibility assessment demonstrate the substantial equivalence of the submission device to the identified primary predicate device.

Therefore, the IS3 can be found substantially equivalent to the Tellos ISQ Buddy.