July 25, 2019

Handpiece Headquarters - HPR Inc.
Sonny Phung
Product Engineer
620 S. Placentia Avenue
Placentia, California 92870

Re: K180845
Trade/Device Name: Maxima Electric System
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: Class I
Product Code: EBW
Dated: April 25, 2019
Received: April 26, 2019

Dear Sonny Phung:

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,

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

Indications for Use

510(k) Number (if known): **K180845**

Device Name: **Maxima Electric System**

Indications for Use:

The Maxima Electric System is intended to convert pneumatic output from a dental treatment center to electrical energy to drive an electric micro motor and to operate electrically- driven dental handpieces. This system is designed for use by a trained professional in the field of general dentistry.

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

510(K) SUMMARY:
K180845

Reference: 510(k) Traditional Premarket Notification for Maxima Electric System

a- Submitted by: HANDPIECE HEADQUARTERS
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Placentia, CA 92870
Tel. 714-579-0175 Fax. 714-579-0186

b- Contact person: Sonny Phung
Tel. 714-579-0175 ext.4871 Fax. 714-579-0186
Email: son.phung@henryschein.com

c- Date summary prepared: July 23, 2019

d- Device Name:

Trade or Proprietary Name: Maxima Electric System

Common Name: Dental Handpiece and accessories

Classification Name: Dental Handpiece and accessories

Classification number: 21CFR 872.4200

Product code: EBW

Class: I

e- Substantial Equivalency is claimed against the following device:

ELECTROtorque TLC4893 with INTRAmatic KL 702 by Kaltenbach & Voight GmnbH
510(k) # K103027

f- Indications for Use

The Maxima Electric System is intended to convert pneumatic output from a dental treatment center to electrical energy to drive an electric micro motor and to operate electrically- driven dental handpieces. This system is designed for use by a trained

professional in the field of general dentistry.

g- Description of the device:

Maxima Electric System is a system attached to dental system to operate Electrically-driven low speed handpieces. The common gear ratio is 1:1 and 1:5, the speed range is from 100 to 40,000 rpm.

Software used on control box is to control speed, forward and reverse direction of the handpieces; turn on an off the cooling water and LED light. There are 3 memories for speed of common low speed handpieces can be save into the program.

The air hose is connect the air and water from 4-hole standard handpiece hose from dental system to the control unit, the existing air pedal from dental system is to turn on and off and control speed by converting pneumatic from dental system to electrical energy to operate electric handpieces.

The control box is power by a power supply AC/DC voltage 36 VDC.

Maxima Electric System consists of the following components:

1-Control Unit
2-Motor Cable
3-Micromotor (Model ELM-B40S)
4-Accessories including the following
a-Foot switch (optional)
b-AC/DC Adapter
c-AC cord

A control unit, Motor Cable and a Micro-motor.

1-Front panel

No.	Description	Function
1	Rotation direction selection button	Used to select the rotational direction (CW/CCW) of the motor and change the mode.
2	Motor operation direction indicator	Displays the current operation direction of the motor (it is turned when the opposite direction is selected).
3	Motor LED ON/OFF button	Used to turn on and off the motor LED and release the mode.
4	Motor LED stated indicator	Displays the set state of the motor LED (LED On means the LED is turned on).
5	Spray button	Used to switch on or off the spray function.
6	Spray state indicator	Displays the operational state of the spray function; water is sprayed when it is On.
7	Speed controller	Used to set the rotational speed and the maximum speed of the motor.
8	Selected gear indicator	Displays the selected gear ratio of the handpiece.
9	Program selection button	Used to save the currently set value in the memory / select a saved program.
10	Gear selection button	Used to select the gear ratio of the handpiece connected to the motor.
11	Speed indicator	Displays the rotational speed of the handpiece.

2-Rear

No.	Description	Function
1	Tubing Connector	Supplies air and water. ※ ISO 9168(type 3)
2	Foot Switch Connector	Connects the control unit with the foot switch.
3	Motor Connector	Serves as a connection to run the micromotor (it cannot be separated from the control unit).
4	Power Switch	Power switch of the control unit.
5	Adapter Connector	Connector through which power gets supplied from the adapter.
6	Motor Cable	Connects the control unit and motor.
7	Motor Cap	Connects the motor and motor cable.

3-Micro Motor (ELM-B40S)

No.	Description	Function
1	Handpiece connector	Connects the micromotor and handpiece. ※ ISO 3964(type 3)
2	Body	Body component through which electrical energy gets converted into rotational motions.
3	LED	LED installed in the motor.

4) AC/DC Adapter, AC Cord

No.	Description	Function
1	AC/DC Adapter	Switches commonly used power input to rechargeable voltage
2	Connection Jack	Connection jack with the control box
3	AC Cord	Power cord connection cable to supply operating voltage

h- Comparison of technological characteristics:

1- Comparison table:

	Subject Device: Maxima Electric System	Predicate: ELECTROtorque TLC4893 with INTRAmatic KL 702
Indication of use	The Maxima Electric System is intended to convert pneumatic output from a dental treatment center to electrical energy to drive an electric micro motor for operation of electrically-driven dental handpieces. This system is designed for use by a trained professional in the field of general dentistry.	The ELECTROtorque TLC4893 is intended to convert pneumatic output from a dental treatment center to electrically energy to drive the INTRAmatic KL 702 motor for operation of electrically-driven handpieces. This devices are designed for use by a trained professional in the field of general dentistry.
Patient contact information	None	None
Device Design:		
Including Components	Power Supply, Control Box, Micro Motor, AC cord.	Power Supply, Control Box, Micro Motor, AC cord.
Control Unit		

Speed control button	Yes	Yes
Speed Range	100-40,000 rpm	100-40,000 rpm
Digital Speed reading	yes	Yes
Rotation Control	Clockwise & Counter Clockwise	Clockwise & Counter Clockwise
Light ON/OFF	yes	Yes
Water Spray ON/OFF	yes	Yes
Programmable setting	3	2
Power Supply		
Voltage input	100-240 VAC	100-240 VAC
Frequency	47-63 Hz	47-63 Hz
Voltage Output	36-38 V DC	36-38 V DC
Power	105 W	120 W
Micro Motor		
Max. Speed	40,000 rpm	40,000 rpm
Dimension	20mm (Diameter) x 63mm (Length)	21mm (Diameter) x 65mm (Length)
Weight	69 gm	69.6 gm
Optic	White LED	White LED
Internal Irrigation	Yes	Yes
Torque	3.0 N-Cm	3.0 N-Cm
Air pressure	4.0 Bar Max.	5.0 Bar
Water pressure	2.5 Bar Max.	2.0 Bar
Coupling dimensions (Micromotor)	According to ISO-3964	According to ISO-3964
Hose connection (connect to 4-hole standard handpiece hose of dental system)	According to ISO-9168	According to ISO-9168

2-Comparison of performance testing:

Based on performance testing results, there are no significant differences in performance of testing handpieces after 250 cycles of testing by using Maxima Electric System and KaVo Electro Torque. The Speed Vs Torque table shows the similar trend of speed and torque from the beginning of the test to the end of 250 cycles of testing.
The performance of the Maxima Electric System on the testing handpiece is similar to the performance of the KaVo Electric torque on the testing the handpiece regarding to Speed Vs Torque.

i- Bench Performance Testing Conducted:

- Risk Analysis per ISO 14971

- Sterilization and cleaning/disinfection validation per ISO 17665-1, ISO 17665-2, and FDA Guidance Document for Reprocessing of Medical Device

- Moderate level of software documentation and verification per the FDA Guidance Document for Software Contained in Medical Devices
- Biocompatibility Assessment per FDA Guidance Document of Use of ISO 10993-1 and Cytotoxicity testing per ISO 10993-5
- EMC and Electrical safety testing per IEC 60601-1 and IEC 60601-1-2
- Evaluation of conformance to ISO 14457, IEC 60601-1-6, IEC 63266, and IEC 80601-2-60.

j- Conclusion:

Base on comparison table, the design and operation of this product has similar intend of use, similar principle of operation and similar technological characteristics such as components for the system, similar control box with software to control speed, similar micromotor, similar connection to dental system and similar performance testing data. Handpiece headquarters believes that this Maxima Electric System is substantially equivalent to the claimed predicated device.