March 4, 2020

J. Mortia USA, Inc.
% Keith Barritt
Attorney
Fish & Richardson P.C.
1000 Maine Ave. S.W. 9th floor
Washington, District of Columbia 20024

Re: K190509
Trade/Device Name: Lubrina 2
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: Class I, reserved
Product Code: EFB
Dated: December 4, 2019
Received: December 5, 2019

Dear Keith Barritt:

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 “Nandu” Nandkumar, Ph.D.
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)*
K190509

Device Name
Lubrina 2

Indications for Use *(Describe)*
The Lubrina 2 is for lubricating and cleaning the inside of dental instruments.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
J. Morita USA Inc.
Lubrina 2

Dental handpiece accessory maintenance, cleaning and lubrication

The following information is provided pursuant to 21 CFR 807.92.

807.92(a)(1): Submitter's Name/Address, Contact, and Preparation Date

(i) 510(k) Submitter

J. Morita USA, Inc.
9 Mason
Irvine, CA 92618
Phone: (949) 581-9600
FDA Reg. No.: 2081055

(ii) 510(k) Submitter Contact

Keith A. Barritt
Fish & Richardson P.C.
1000 Maine Ave. S.W.
Washington, DC 20024
Phone: (202) 783-5070
Facsimile: (202) 783-2331
Email: barritt@fr.com

(iii) Preparation Date

March 4, 2020

807.92(a)(2): Name of Device

Trade or Proprietary Name:	Lubrina 2
Model Name:	HIM-2
Common Name:	Dental handpiece accessory maintenance, cleaning and lubrication
Classification Name:	Dental handpiece and accessories
Primary Product Code:	EFB
Classification Panel:	872 Dental
Regulation:	21 CFR 872.4200

807.92(a)(3): Predicate Devices

The Lubrina 2 device is substantially equivalent for purposes of FDA medical device regulations to J. MORITA MFG CORP.'s own Lubrina (Model HIM-1) (K#070074).

The Lubrina 2 has similar indication for use, similar principles of operation, and similar technological characteristics as the previous cleared Lubrina. Although there are minor differences in the characteristics between the Lubrina 2 and the original Lubrina, these differences do not raise new questions of safety or effectiveness.

807.92(a)(4): Device Description

The Lubrina 2 device is used to maintain optimum performance and prolong the working life of dental handpieces. The Lubrina 2 delivers oil and air automatically to handpieces, and is used after dental treatment and before autoclaving. The Lubrina 2 is not installed in a dental operative unit, but rather is to be used on a table or shelf.

There is only one model. The type varies depending on the country/area the device is to be shipped to and the power cord for that region is included in the package. For the USA, only model HIM-2 Type US, is to be marketed, together with the power cord for the USA.

Operating Mechanism:

The Lubrina 2 supplies lubrication oil to the inside of handpieces by automatically discharging pressurized air from spray can lubricant. Excess oil is removed from the handpiece by pressurized air.

The Lubrina 2 has four operation modes:

- Chuck Lubrication
- Handpiece Body Lubrication
- Flushing (Extended lubrication)
- Air blow mode

The accompanying items/components and the optional items are identified further in the charts below:

Accompanying Items

Name	Function	Note
Oil Absorbent Pad	Absorbing the drained oil in exhaust part	consumable; included in prior 510(k) submission for Lubrina K#070074
Oil Absorbent Sheet	Absorbing the drained oil in internal body	consumable; included in prior 510(k) submission for Lubrina K#070074
Power Cord	Electric power code for the USA	included in prior 510(k) submission for Lubrina K#070074
Air Tube	Providing air to main body	included in prior 510(k) submission for Lubrina K#070074
Door Oil Absorbent Sheet	Absorbing oil on the front door	consumable; not included in prior 510(k) submission for Lubrina K#070074
Front Door Sheet Stopper	Fixing the above Door Oil Absorbent Sheet	not included in prior 510(k) submission for Lubrina K#070074
Nozzle skirt	To prevent oil splashes during the chuck maintenance described in 7.3.2 of IFU	consumable; included in prior 510(k) submission for Lubrina K#070074

Accompanying Spray Stands for Compatible Sprays

Name	Function	Note
MORITA stand	A stand to fit the Morita type spray can to the Lubrina 2	part of original Lubrina K#070074
KaVo stand NSK stand YOSHIDA stand	A stand to fit the KaVo, NSK, and YOSHIDA type spray can to the Lubrina 2	not included in prior 510(k) submission for Lubrina K#070074
W&H stand	A stand to fit the W&H type spray can to Lubrina 2	not included in prior 510(k) submission for Lubrina K#070074
Sirona stand	A stand to fit the Sirona type spray can to Lubrina 2	not included in prior 510(k) submission for Lubrina K#070074
Bien-Air stand	A stand to fit the Bien-Air type spray can to Lubrina 2	not included in prior 510(k) submission for Lubrina K#070074

Optional Items

Name	Function	Note
Alpha Coupling	To connect handpieces with alpha joint to Lubrina 2	not included in prior 510(k) submission for Lubrina K#070074
LS Coupling	To connect low speed handpieces (ISO3964 conformed) to Lubrina 2	not included in prior 510(k) submission for Lubrina K#070074
4H Coupling	To connect handpieces with 4-H joint to Lubrina 2	not included in prior 510(k) submission for Lubrina K#070074
KaVo Coupling	To connect handpieces with Kavo joint to Lubrina 2	not included in prior 510(k) submission for Lubrina K#070074

Name	Function	Note
W&H Coupling	To connect handpieces with W&H joint to Lubrina 2	not included in prior 510(k) submission for Lubrina K#070074
Sirona Coupling	To connect handpieces with Sirona joint to Lubrina 2	not included in prior 510(k) submission for Lubrina K#070074
TR-ZX2/DP Coupling	To connect J. Morita handpieces (TR-ZX2, DP-ZX-VL, and TR-CM) to Lubrina 2	not included in prior 510(k) submission for Lubrina K#070074
Tri Auto ZX Coupling	To connect Morita handpieces (TR-ZX) to Lubrina 2	included in prior 510(k) submission for Lubrina K#070074
Coupling Rubber Gasket	Gasket for couplings which conforms to ISO9168 type 3	not included in prior 510(k) submission for Lubrina K#070074

807.92(a)(5): Indication for Use

The Lubrina 2 is for lubricating and cleaning the inside of dental instruments.

807.92(a)(6): Technological Characteristics

A comparison table of the technological characteristics of the Lubrina 2 and the predicate devices appears below:

	Submission Device	Predicate	Comparison result
Product name	Lubrina 2	Lubrina	-
Model	HIM-2	HIM-1	-
Manufacturer	J. MORITA MFG. CORP.	J. MORITA MFG. CORP.	Identical
510(k) Number		K070074	-
Indication for use	The Lubrina 2 is for lubricating and cleaning the inside of dental instruments	LUBRINA HIM-1 is intended for internal cleaning, i.e., purging of old lubricant, for the maintenance of rotating dental and surgical instruments. NOTE: LUBRINA HIM-1 should be used only with pre-cleaned dental handpieces and before they are sterilized.	Substantially identical
Target population	Dentist, doctor, dental hygienist or medical staff. It is not used to the patient.	Dentist, doctor, dental hygienist or medical staff. It is not used to the patient.	Identical
Where used	Dental clinic, university hospital and the other clinical settings	Dental clinic, university hospital and the other clinical settings	Identical
Energy used and/or delivered	Rating AC100-240V Input 10-25VA Voltage 100-240V Frequency 50/60Hz Air Pressure 0.3-0.5MPa	Rating AC100-240V Input 10-25VA Voltage 100-240V Frequency 50/60Hz Air Pressure 0.3-0.5MPa	Identical
Design	Appearance New design Size W300×D300×H365mm	 Size W300×D300×H370mm	Similar
Performance	- The maximum 4 pieces of handpieces are able to be connected. - Two spray cans are set inside the box. Maximum processing time:40sec/piece	- The maximum 4 pieces of handpieces are able to be connected. - Two spray cans are set inside the box. Maximum processing time:120sec/piece	Similar Reduced processing time compared to the Lubrina Reduced operating noise compared to the Lubrina
Standards met	ISO 14971:2007, Corrected Version 2007-10-01 IEC62366:2007+A1 2014 ISO152231:2016,Corrected version2017-03 IEC60601-1:2005/A1:2012 IEC60601-1-2:2014 IEC60601-1-6:2010 IEC62304:2006	ISO 14971:2007, Corrected Version 2007-10-01 IEC62366:2007+A1 2014 ISO152231:2016,Corrected version2017-03 IEC60601-1:2005/A1:2012 IEC60601-1-2:2014 IEC60601-1-6:2010 IEC 62304:2006	Identical
Materials	Metal: ・Stainless steel ・Hot-dip zinc-coated steel ・Aluminum ・Copper alloy ・Neodymium magnet Plastic ASA, PPS, PVC, POM, PP Rubber Nitrile, Silicone, Fluoride	Metal: ・Stainless steel ・Hot-dip zinc-coated steel ・Cold reduced carbon steel sheets ・Aluminum ・Copper alloy Plastic PBT/ABS, PPS, POM, PP Rubber Nitrile, Silicone, Fluoride	Similar

	Submission Device	Predicate	Comparison result
Product name	Lubrina 2	Lubrina	-
Model	HIM-2	HIM-1	-
Electrical safety	In accordance with IEC60601-1, EN 62304 and ISO 14971	In accordance with IEC60601-1, EN 62304 and ISO 14971	Identical
Radiation safety	In accordance with IEC60601-1- 2	In accordance with IEC60601-1-2	Identical
Mechanical safety	In accordance with IEC60601-1 and ISO 14971	In accordance with IEC60601-1 and ISO 14971	Identical
Thermal safety	In accordance with IEC60601-1	In accordance with IEC60601-1	Identical
Anatomical sites	Not applicable	Not applicable	Identical This device is not used to the patient.
Sterility	Not applicable	Not applicable	Identical This device is not used to the patient.
Human factors	In accordance with IEC62366	In accordance with IEC62366	Identical
Compatibility with environment and other devices	Conform to IEC60601-1-2	Conform to IEC60601-1-2	Identical

807.92(b)(1): Non-clinical Testing

The Lubrina 2 was tested for compliance and/or developed in accordance with the following international standards:

IEC60601-1:2005/A1:2012 Medical Electronic Equipment

This testing is designed to ensure the electrical safety of the device.

IEC 60601-1-2:2014 Electromagnetic Compatibility

This testing is designed to ensure the electromagnetic compatibility of the device when operated in its expected use environment.

IEC 60601-1-6:2010+A1:2013 Usability

This testing is designed to ensure reasonable device usability to minimize use errors and use-associated risks.

IEC 62304:2006 Medical Device Software

This testing is designed to ensure the software fulfills its intended purpose without causing any unacceptable risks. Software documentation was provided pursuant to the FDA's "Guidance for the Content of Premarket Submission for Software Contained in Medical Devices."

IEC 62366 :2007+A1 2014 Medical Devices – Application of Usability Engineering

> This testing is designed to analyze, specify, design, verify and validate usability as it relates to safety of a medical device. This usability engineering process assesses and mitigates risks caused by usability problems associated with correct use and use errors, i.e. normal use.

ISO 14971: 2007, Corrected Version 2007-10-0 - Application of Risk Management to Medical Devices

> This standard provides a framework for systematically managing the risks associated with the use of medical devices. It addresses processes for managing risks, primarily to the patient, but also to the operator, other persons, other equipment, and the environment.

ISO 15223-1:2016 Medical Devices – Symbols Used with Medical Device Labels

> This standard identifies requirements for symbols used in medical device labeling that convey information on the safe and effective use of medical devices.

Testing was conducted to confirm that the device is capable of lubrication and cleaning handpieces and the device was shown to be substantially equivalent to the predicate. Performance bench testing was conducted to demonstrate the compatibility of the device with various lubricating cans.

In summary, the non-clinical testing establishes that the device is substantially equivalent to the predicate device.

807.92(b)(2): Clinical Testing

> There were no clinical tests performed for Lubrina 2.

807.92(b)(3): Conclusions from Testing

> Based on the comparison of Lubrina 2 to the predicate device identified above, and based on the data gathered in the non-clinical testing described above, it is concluded that the data provided in this 510(k) submission demonstrates that Lubrina 2 is substantially equivalent to the predicate devices.