K061701

AUG 25 2006

510(k) SUMMARY

J. MORITA USA Inc.'s

TWIN POWER TURBINE 4H

1. Submitter Name and Address with Phone/Fax :

Registration No. 2081055
Initial Distributor:
J. Morita USA, Inc.
9 Mason
Irvine, CA 92618
USA
Telephone: 949-581-9600
Facsimile: 949-581-9688

Registration No. 3002807636
Manufacturer:
J. MORITA MFG. CORP.
680 Higashihama Minami-cho
Fushimi-ku, Kyoto
Japan 612-8533
+81-75-611-2141
+81-75-605-2354

2. Contact Person :

Keith A. Barritt
Fish & Richardson P.C.
1425 K Street, N.W.
Suite 1100
Washington, DC 20005
Phone: (202) 783-5070
Facsimile: (202) 783-2331

3. Date summary prepared: May 15, 2006

4. Device Name:

Trade or Proprietary Name::
TWIN POWER TURBINE 4H (High Speed Air Turbine Dental Handpiece)

Models; PAR-4HEX/4HX series (Details are listed at Table-1 in page 3 of this submission.)

Common Name: Air powered dental handpiece

Classification Name: Dental handpiece and accessories
(21CFR 872.4200)

Product Code : EFB ("Handpiece, Air-powered, Dental ")

5. Substantial Equivalency is claimed against the following device:

PAR-4HE-O of J. MORITA MFG. CORP.(K043498)

6. Description of the device:

Ⅶ-1 DEVICE DESCRIPTION

TWIN POWER TURBINE 4 H is a dental handpiece.

Through the tube connected to a dental unit, the handpiece of this device receives the air for high speed turbine, the cooling water for cutting treatment through pouring holes and light for illumination source.

The PAR-4HEX/4HX series includes ten types of models as is shown below at Table-1, and they are be able to be connected to the coupling of the other manufacturers than J.MORITA .

Table-1 PAR-4HEX/4HX series

Name	Model	Main Body		Coupling	
		Body	Head assembly	PAR- 4 Hole coupling	Tube connection ISO9168
TWIN POWER TURBINE 4 H	PAR- 4 HEX-O	PAR- 4 HEX-O	Standard type	JMORITA MFG. CORP. CP4-O, CP4-WO, CP4-CS-O	Type-C in case of "with light"
	PAR- 4 HEX-O-KV	PAR- 4 HEX-O-KV-		KAVO MULTIflex, MULTIflex LUX	
	PAR- 4 HEX-O-NK	PAR- 4 HEX-O-NK		NSK Phatelus coupling	
	PAR- 4 HEX-O-SR	PAR- 4 HEX-O-SR		SIRONA R/F coupling	
	PAR- 4 HEX-O-WH	PAR- 4 HEX-O-WH		W&H Roto Quick coupling	
	PAR- 4 HX-O	PAR- 4 HX-O	Torque-up type	JMORITA MFG. CORP. CP4-O, CP4-WO, CP4-CS-O	Type-B in case of "without light"
	PAR- 4 HX-O-KV	PAR- 4 HX-O-KV		KAVO MULTIflex, MULTIflex LUX	
	PAR- 4 HX-O-NK	PAR- 4 HX-O-NK		NSK Phatelus coupling	
	PAR- 4 HX-O- SR	PAR- 4 HX-O-SR		SIRONA R/F coupling	
	PAR- 4 HX-O-WH	PAR- 4 HX-O-WH		W&H Roto Quick coupling	

NOTE:

1. Suffix "-O" is a sign for " with light" .
   There are models without light in the series whose suffix "-O" is removed away from the name.
   For example, PAR-4 HX-O- KV is " with light" and PAR- 4 HX- KV is "without light" , and so on.
   It is also applicable for the names of PAR- 4 Hole coupling made by JMORITA such as CP4-O, CP4-WO or CP4-CS-O (with light) and CP4, CP4-W or CP4-CS (without light).

2. Suffix "-ML" is attached to the last of the model name when the metal ball bearing is assembled in the handpiece, for instance, PAR- 4 HX-O- KV-ML or so.

7. Indications for Use

The PAR-4HEX/ 4 HX series handpiece is for use by authorized persons in the practice of the dentistry.

8. Safety and effectiveness of the device

TWIN POWER TURBINE is only slightly modified from our Previous PAR- 4 H (K043498) , by adding some new phases such as;.

1. Coupling
This new model is able to be connected to the coupling manufactured and/or distributed by the other manufacturers more than the coupling of J. MORITA MFG. CORP.
2. A new function, Zero suck back function, is added on the previous specifications.

However, the PAR-4HEX/4HX series is substantially equivalent to our previous PAR-4H series (K043498) because they have similar general intended uses, technological characteristics and operating principles.

Any differences in the technological characteristics do not raise any new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

J. Morita USA, Incorporated
C/O Mr. Keith A. Barritt
Attorney
Fish & Richardson P.C.
1425 K Street, N.W. Suite 1100
Washington, DC 20005

AUG 2 5 2006

Re: K061701
Trade/Device Name: PAR-4HEX/HX Series Handpiece
Regulation Number: 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EFA
Dated: June 15, 2006
Received: June 16, 2006

Dear Mr. 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. 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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): unknown K061701

Device Name: PAR-4HEX/HX series handpiece

Indications For Use:

The PAR-4HEX/4HX series handpiece is for use by authorized persons in the practice of the dentistry.

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

Sign-Off)
n of Anesthesiology, General Hospital,
on Control, Dental Devices
Number K061701