K063529

Attachment-6

510(k) SUMMARY
J. Morita USA Inc.'s Pencure VL-7

JAN - 5 2007

1. Submitter Name and Address with Phone/Fax :

Registration No. 2081055	Registration No. 3002807636
Initial Distributor:	Manufacturer:
J. Morita USA, Inc.	J. MORITA MFG. CORP.
9 Mason	680 Higashihama Minami-cho
Irvine, CA 92618	Fushimi-ku, Kyoto
USA	Japan 612-8533
Telephone: 949-581-9600	+81-75-611-2141
Facsimile: 949-581-9688	+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:

November 08, 2006

4. Device Name:

Common/Usual Name:	Dental curing light
Trade or Proprietary Name:	PENCURE
Product Model Name ;	VL-7
Regulation Number:	21 CFR § 872.6070
Regulation Name :	Ultra violet activator for polymerization.
Regulatory Class :	II
Product Code:	EBZ
Classification Panel:	872 Dental.

5. Substantial Equivalency is claimed against the following device:

The VL-7 covered by this submission is substantially equivalent to other legally marketed Ultraviolet activators.

1) Predicate device I

The VL-7 is substantially equivalent to the JETLITE5000 from J.MORITA USA.INC. , (K#051780). The VL-7 has similar general intended uses, similar principles of operation, and similar technological characteristics as the previously cleared predicate JETLITE5000.

2) Predicate device II

The VL-7 is substantially equivalent to the SmartLite™ PS Pen-Style LED Curing Light from DENTSPLY DeTrey GmbH (K#041372). The VL-7 has similar general intended uses, similar principles of operation, and similar technological characteristics as the previously cleared predicate SmartLite™ PS Pen-Style LED Curing Light .

Although there are minor differences in the characteristics of the VL-7and its predicate devices, these differences do not raise new questions of safety or effectiveness.

6. Description of the device

The VL-7 is a dental curing light manufactured by J. MORITA MFG. CORP.
The VL-7 is to be used at the dental treatment of curing polymer cement by the dentist.

The VL-7 delivers an optimum wavelength of between 420 and 480nm by using blue LED. Its powerful light beam is directly irradiated on polymer material.

There are three characteristics.

1. The irradiated beam is almost the same as parallel. Therefore, the percentage of reducing light intensity is lower.
2. The cordless handpiece can be easily positioned at molars.
3. The head part of the handpiece is able to be rotated around the axis of handpiece.

7. Indications for use

The Pencure is intended to polymerize (set) resinous dental pit and fissure sealants or dental restorative materials by light from head.

8. Safety and effectiveness of the device

This device is safe and effective as the other predicate device cited above.
This is better expressed in the tabulated comparison (Paragraph 9 below).

9. Substantial Equivalent comparison table

FDA file reference number 510k number K051780 and K041372.
Attachment inside notification submission file 510k FDA website print out

Model name of Predicate Device	JETLITE 5000	SmartLite™ PS Pen-Style LED Curing Light
510(k) number of Predicate Device	K051780	K041372
TECHNOLOGICAL CHARACTERISTICS	Comparison result	Comparison result
Indication for use	Similar	Similar
Target population	Identical	Identical
Design	Similar	Similar
Materials	Presumed similar	Presumed similar
Performance	Similar	Similar
Sterility	Similar	Similar
Biocompatibility	Presumed similar	Presumed similar
Mechanical safety	Similar	Presumed similar
Chemical safety	Similar	Presumed similar
Anatomical sites	Identical	Identical
Human factors	Identical	Identical
Energy used and/or delivered	Similar	Similar
Compatibility with environment and other devices	Similar	Similar
Where used	Identical	Identical
Standards met	Presumed similar	Presumed similar
Electrical safety	Similar	Presumed similar
Thermal safety	Presumed similar	Presumed similar
Radiation safety	Similar	Similar

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, Esq.
Fish & Richardson P.C.
1425 K Street N.W., Suite 1100
Washington, District of Columbia 20005

JAN 0 5 2007

Re: K063529
Trade/Device Name: Pencure VL-7
Regulation Number: 21 CFR 872.6070
Regulation Name: Ultraviolet Activator for Polymerization
Regulatory Class: II
Product Code: EBZ
Dated: November 21, 2006
Received: November 24, 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.

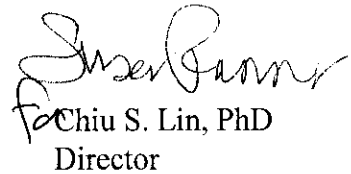
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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" (21 CFR 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



for Chiu S. Lin, PhD
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 : ~~unknown~~ K063529

Device Name: Pencure

Indications for Use:

The Pencure is intended to polymerize (set) resinous dental pit and fissure sealants or dental restorative materials by light from head.

Prescription Use ✓ AND/OR Over-The-Counter Use

(Part21CFR801 Subpart D) (Part21CFR807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation(ODE)

Susan Runner

(Division Sign-Off)

Division of Anesthesiology, General Hospital,

Infection Control, Dental Devices

510(K) Number : K063529

Prescription Use ✓ or Over-The-Counter Use

(Part21CFR801.109) (Optional Format 1-2-96)