510(k) SUMMARY

K090925

J. MORITA USA Inc.'s
RCM-7

NOV 2 3 2009

1. NAME OF DEVICE

Common/Usual Name: Apex Locator

Device trade or proprietary name: Multiple (Apex Locator)
*The device may be sold under multiple product names including Root ZX mini.

Product Model Name : RCM-7

2. 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

3. 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

4. DATE SUMMARY PREPARED: March 19, 2009

5. DEVICE CLASSIFICATION/CLASSIFICATION PANEL

Device:	Locator, Root Apex
Review Panel:	872 Dental
Product Code:	LQY
Device Class:	Unclassified

6. DEVICE DESCRIPTION/SUBSTANTIAL EQUIVALENCE

DEVICE DESCRIPTION

The RCM-7 is a dental device, Apex Locator.
It can be used to detect the apex of root canal.

SUBSTANTIAL EQUIVALENCE

The RCM-7 is substantially equivalent to Root ZX (K921979 / K953867) and the Canal Measurement Module of DP-ZX-VL (K071190).

1) Predicate device I : Root ZX (K921979 / K953867)
The RCM-7 is substantially equivalent to Root ZX from J.MORITA MFG.CORP. The RCM-7 has similar general intended uses, similar principles of operation, and similar technological characteristics to the predicate device Root ZX (K921979 / K953867).

2) Predicate device II : DP-ZX-VL (Device Name: ROOT ZX II) (K071190)
The RCM-7 is substantially equivalent to the Canal Measurement Module of the DP-ZX-VL (K071190) from J.MORITA MFG.CORP. The RCM-7 has similar general intended uses, similar principles of operation, and similar technological characteristics to the predicate device, DP-ZX-VL (K071190).

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

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Table- 1 **Comparison summary table**

	Predicate devices	
TECHNOLOGICAL CHARACTERISTICS of RCM-7	**Root ZX (K921979 / K953867)**	**DP-ZX-VL (K071190)**
Indication for use Canal Measurement Function	**Identical**	**Identical**
Canal Preparation Function Light Cure Function		**Different**
Target population	**Identical**	**Identical**
Design	**Similar**	**Similar**
Materials	**Similar**	**Similar**
Performance Canal Measurement Function	**Identical**	**Identical**
Canal Preparation Function Light Cure Function		**Different**
Sterility	**Similar**	**Similar**
Biocompatibility	**Similar**	**Similar**
Mechanical safety	**Identical**	**Identical**
Chemical safety	**Identical**	**Identical**
Anatomical sites	**Identical**	**Similar**
Human factors	**Identical**	**Similar**
Energy used and/or delivered	**Identical**	**Similar**
Compatibility with environment and other devices	**Similar**	**Similar**
Where used	**Identical**	**Identical**
Standards met	**Similar**	**Identical**
Electrical safety	**Similar**	**Identical**
Thermal safety	**Identical**	**Identical**

7. INDICATIONS FOR USE

RCM-7 is a dental device, Apex Locator.
It can be used to detect the apex of root canal.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

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

NOV 23 2009

Re: K090925
Trade/Device Name: Multiple (Apex Locator)
Regulation Number: Unclassified
Regulation Name: None
Regulatory Class: Unclassified
Product Code: LQY
Dated: November 16, 2009
Received: November 17, 2009

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 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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

Susan Runner, D.D.S., M.A.
Acting 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): 090925

Device Name: Multiple (Apex Locator)

Indications For Use:

RCM-7 is a dental device, Apex Locator.

It can be used to detect the apex of root canal.

Prescription Use X 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)

Ron Mackey for MSE

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K090925