K022147

510(k) SUMMARY

J. Morita Manufacturing Corporation's DENTA PORT Dental Device

DEC 2 0 2002

Name of Device and Name/Address of Sponsor

Trade or Proprietary Name:	DENTA PORT
Common Name:	dental handpiece and root canal length measuring device
Classification Name:	AC-Powered Dental Handpiece and Root Apex Locator
Product Code :	EKX and LQY

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Date Prepared: June 25, 2002

Intended Use

The DENTA PORT is a dental root canal measurement and treatment device that can measure the length of the root canal and enlarge the canal while monitoring the position of the file tip inside the canal.

Technological Characteristics and Substantial Equivalence

The DENTA PORT is composed of a canal measurement base module (the DP-RCM module) and a canal enlargement module (the DP-TR module).

The DP-RCM module can be used alone and has a root canal measurement capability. It can be used to measure the length of the canal.

The DP-TR module can be used only when it is connected to the DP-RCM module. When connected, it can be used to enlarge canals while monitoring the position of the file tip inside the canal. It can be used to measure the length of the canal, and it can be used as a low speed motorized handpiece.

The DP-RCM base module

The root canal length can be measured in a simple and safe way by measuring electrical impedance (400, 8000 Hz) between the electrode (root canal file) located inside of the opened root canal and an oral mucous electrode, calculating the ratio of two impedance values, and thereby indicating the position of the file tip inside the root canal. This allows the dentist to safely and efficiently perform canal enlargements of root canals.

1) The DENTA PORT requires no adjustments or calibrations and can be used whether the canal is dry or filled with strong electrolytes such as blood, hydraulic saline, etc. The size of the file has almost no effect on the measurement.
2) Since the position of the file tip and the meter reading are directly related, root canal enlargement can easily be performed while continuously monitoring the length of the canal electrically.
3) The meter is an easy-to-read liquid crystal display.
4) The position of the file tip is easily determined by the changes in the monitor's audible signals.
5) The unit is powered by commonly available "AA" batteries. Low power consumption enhances long battery life.
6) The file holder and contrary electrode can be autoclaved.

The DP-TR module connected to DP-RCM base module

The DP-TR module connected to the DP-RCM module has the same functions as the DP-RCM module alone, such as root canal measurement, plus it has a dental micromotor and can be used with root canal files. With the accompanying root canal files, the DP-TR enables the mechanical preparation of dental root canals and the removal of gutta-percha points. During the mechanical preparation of the dental root canal, the device measures electrical impedance (400, 8000 Hz) between the file electrode connected to the root canal and an oral mucous electrode by calculating the ratio of two impedance values and indicating the position of the file tip inside the root canal. The device also uses this information for motor movement. This allows the dentist to safely and efficiently perform the mechanical preparation of root canals and the mechanical removal of gutta-percha points.

The DP-TR module has the following features.

1) Auto Start / Stop
2) Auto Apical Reverse
3) Auto Torque Reverse
4) Two types of motors are available.
5) The position of the file tip is monitored and displayed while the canal is being enlarged.
6) In manual mode, the motor rotates even when the file is outside the root canal. When the files are inside the root canal, the device switches to automatic mode.
7) A foot switch is available. When it is turned on, the motor rotates even when the file is outside the root canal. When the file is inside the root canal, the device switches to automatic mode.
8) Auto slow down is available. When auto slow down is set, the motor rotation speed is reduced automatically when the tip of the file comes near the apex.
9) Files are easy to replace by the push chuck.
10) The volume of the audible signals can be adjusted or turned off.
11) The contra head, file holder, and contrary electrode can be autoclaved as long as the temperature does not exceed 135°C.
12) Only nickel-titanium files can be used with the DP-TR module for mechanical preparation of inside the root canal.
13) A rechargeable battery is used for power supply.

The DENTA PORT is substantially equivalent to the Tri Auto ZX (K#970339) because both devices have similar general intended uses, technological characteristics, and operating principles.

The principal differences in the technological characteristics between the DENTA PORT and the Tri Auto ZX are: (1) the DENTA PORT is composed of two modules; (2) the motor of the DENTA PORT has tubing and the Tri Auto ZX does not; (3) the free running speeds are different; (4) the DENTA PORT has two types of motors while the Tri Auto ZX has one; (5) the DENTA PORT has an auto slow down feature; (6) the DENTA PORT uses an LCD while the Tri Auto ZX uses an LED display; and (7) the DENTA PORT has a foot switch.

These differences do not raise any new issues of safety or effectiveness. As such, the DENTA PORT raises no new issues of safety or effectiveness.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 0 2002

J. Morita Manufacturing Company
C/O Mr. Keith Barritt
Fish & Richardson P.C.
1425 K Street, N.W. 11th Floor
Washington, D.C. 20005

Re: K022147
Trade/Device Name: DENTA PORT
Regulation Number: None and 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: Unclassified and I
Product Code: LQY and EKX
Dated: October 10, 2002
Received: October 11, 2002

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 (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K#022147

Device Name: DENTA PORT

Indications for Use:

The DENTA PORT is a dental root canal measurement and treatment device that can measure the length of the root canal and enlarge the canal while monitoring the position of the file tip inside the canal.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

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Susan Runner

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

510(k) Number K022147