SEP 11 1997 K972407

I. Summary of Safety and Effectiveness - 510(k) Summary

1. Submitter Information:

Toei Electric Co., Ltd.
771, Shimosakunobe
Takatsu-ku, Kawasaki
Kanagawa-ken 213
Japan
(81)(44)877-5410

Contact Person: Robert P. Reznick, Esq.
Hughes Hubbard & Reed LLP
1300 I Street, N.W.
Washington, D.C. 20005
(202) 408-3740

2. Device Information:

Root canal length measurement device. This device is not classified.

3. Predicate Device:

Root ZX, K953867, K921979

4. Device Description:

The subject device is a lightweight, fully-automatic, battery-operated device that allows a dentist or oral surgeon to locate a patient's anatomical root canal apex and obtain accurate root canal length measurements. The device allows the relative position of a dental file and the apex to be determined electrically. Using a standard dental file inserted into the root canal as an electrode, the device emits very small electrical currents having frequencies of 500 Hz and 2000 Hz. The impedance between the file and mouth is measured at each of these frequencies, and compared, with a readout of the relative proximity to the apex appearing on a stabilized meter. The use of two frequencies minimizes errors introduced by blood or other conducting medicinal fluids in the root canal.

The subject device consists of a main body, incorporating the panel meter, a probe cord and reel, a canal instrument holder, a mouth angle clip, a saliva ejector clip, and batteries. The device operates on four AAA 1.5 v. batteries.

The subject device is intended to be used to measure the length of the root canal for the purpose of performing root canals and related dental procedures.

5. Comparison With Predicate Device:

Device Characteristics	**Subject Device**	**Root ZX**
Power source	4 AAA batteries	5 AA batteries
Electric current	Less than 10 μA	Less than 10 μA
Method of calculating location of root canal apex	Comparison of impedance at 2 frequencies	Comparison of impedance at 2 frequencies
Frequencies used for comparison	500 Hz & 2,000 Hz	400 Hz & 8,000 Hz
Number of cycles used for measurement	2	2
Display	Analog	Liquid crystal
Adjustment before measurement	Unnecessary	Unnecessary
Measuring voltage	50 mV	80 mV
Audio location indicator	Yes	Yes
Weight	Approx. 280g	Approx. 550g
Use with standard dental files	Yes	Yes
Automatic on/off switch	Yes	No

The Subject device and the Root ZX utilize the same method of calculating root canal lengths by comparing electrical impedances at two frequencies and are substantially equivalent in all particulars.

6. Non-Clinical Data Necessary To A Finding Of Substantial Equivalence:

The accuracy of the subject device was confirmed using an in vitro testing model against measurements obtained physically, radiographically, and using an Ingle's calculated length. Measurements were taken in sample extracted teeth having both straight and curved canals. Measurements were also made under conditions in which the teeth were dry and in which they were in the presence of saline and 2.5% sodium hypochlorite solutions. The tests showed no significant difference between the subject device and the predicate in obtaining tooth length in each of the three media tested. Moreover, no significant statistical differences were found between readings taken by the subject device and Ingle's method.

Submitted June 26, 1997

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 11 1997

Mr. Robert P. Reznick
TOEI Electric Company, LTD
C/O Hughes, Hubbard & Reed LLP
1300 I Street, N.W.
Washington, DC 20005

Re: K972407
Trade Name: Root Apex Locator
Regulatory Class: Unclassified
Product Code: LQY
Dated: June 26, 1997
Received: June 26, 1997

Dear Mr. Reznick:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

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

Enclosure

510(k) Number (if known):_____

Device Name: Root apex locator

Indications For Use:

Measurement of the length of the root canal for the purpose of performing root canals and related dental procedures.

(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 Dental, Infection Control, and General Hospital Devices
510(k) Number K978407

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)