JUL - 2 2002

K022020

EXHIBIT 2

TOEI ELECTRIC CO., LTD.
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Contact: Masahiro Fujita, President

510(k) Summary of Safety and Effectiveness

1. Identification of the Device:
   Proprietary-Trade Name: "JUSTWO" Model TME-601 Root Apex Locator
   Classification Name: LQY
   Common/Usual Name: Root Apex Locator
   This device has not been classified.

2. Equivalent legally marketed device: Toei Electric Co. Ltd "Root Apex Locator" K972407

3. Indications for Use (intended use) The device is for measurement of the length of the root canal for the purpose of performing root canals and related dental procedures.

4. Description of the Device: 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 current 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. Safety and Effectiveness, comparison to predicate device:

Device Characteristics	Subject Device (K972407)	Modified Device
Name	"Root Apex Locator"	"JUSTWO" Model TME-601 Root Apex Locator (New name for device)
Power source	4 AAA batteries	SAME
Electric current	Less than 10 μA	SAME
Method of calculating location of root canal apex	Comparison of "impedance" at 2 frequencies (Unit actually measured current, not impedance)	Measurement of **current** at 2 frequencies
Frequencies used for comparison	500 Hz & 2,000 Hz	SAME
Number of cycles used for measurement	2	SAME
Display	Analog	SAME
Adjustment before measurement	Unnecessary	SAME
Measuring voltage	50 mV	SAME
Audio location indicator	Yes	SAME
Weight	Approx. 280 grams	SAME
Use with standard dental files	Yes	SAME
Automatic on/off switch	Yes	SAME

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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 2 2002

Toei Electric Company, Limited
C/O Daniel Kamm, P.E.
Regulatory Engineer
Kamm & Associates
P.O. Box 7007
Deerfield, Illinois 60015

Re: K022020
Trade/Device Name: JUSTWO Model TME-601 Root Apex Locator
Regulation Number: Unclassified
Regulation Name: Root Apex Locator
Regulatory Class: Unclassified
Product Code: LQY
Dated: June 18, 2002
Received: June 20, 2002

Dear Mr. Kamm:

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.

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), 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,

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

k) Indications for Use

510(k) Number K022020

Device Name: "JUSTWO" Model TME-601 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, for use by a trained professional in general dentistry.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the Counter Use_____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K022020