Forum Engineering Technologies (96) Ltd.		
Detect 510(k) File	**Detect 510(k) Summary**	**Rev. 01**
Document number: 5-P22-003.FDA	**Effective Date: Apr 8, 2012**	**Page 1 of 5**

K121206

"510(k) Summary"

Detect, Electronic Apex Locator

JAN 10 2013

The following 510(k) Summary of Safety and Effectiveness has been prepared pursuant to requirements for 510(k) summaries specified in 21 CFR § 807.92(a).

Section's content

5.1. Owner & Submitter Details: [807.92(a)(1)]

Owner & Submitter Name:	Forum Engineering Technologies (96) Ltd.
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5.2. **Candidate Device Details:** [807.92(a)(2)]

Trade Name:	Detect – Electronic Apex Locator
Common Name:	Apex Locator
Classification Name:	Locator, Root Apex
Product Code:	LQY – Locator, ROOT APEX
Review Panel:	Dental
Device Class:	Unclassified

5.3. **Cleared Device Identification:** [807.92(a)(3)]

Devices to which substantial equivalence is claimed:

Table 5.3: Predicate Device Identification

Cleared Device Name	Name of Manufacturer	510(k) Number
BINGO PRO	Forum Engineering Technologies (96) Ltd.	K111474

5.4. **Device Description:** [807.92(a)(4)]

Detect is a modern apex locator intended for precise localization of root canal apex.

The measurements in Detect are performed utilizing AC signals at two frequencies – 500 Hz and 8 kHz. The frequencies are alternated and not mixed, eliminating the need for signal mixing and frequency discrimination electronic circuits. The patented signal measuring method utilized in Detect is based on measurements of RMS (Root Mean Square) level of the signal.

Advanced user interface implemented in Detect is based on high resolution TFT color graphic display. Clear real time presentation of endodontic file movement inside the canal is designed to make dentist's work easier and to increase his confidence. Display indicators are carefully designed to be intuitively understood and to serve for instant troubleshooting during device usage.

Detect shows the movement of the file inside the canal from the beginning of the measurements to the end, providing uninterrupted feedback to the dentist. File tracking algorithm enables full-scale display of the file movement during the treatment while Apical Zoom feature enables high-resolution indication of the file advance in pre-apical and apical zones. Large, clearly recognizable graphical and numerical readings in Apical Zoom are designed to enable precise control over the file advance matching the individual technique of the dentist. Visual information is accompanied by optional audio signals. Numerical values and the numerical scale shown in the Apical Zoom do not represent actual distance from the

apex in mm; they serve as a convenient reference to judge the file tip position in relation to the apex.

Operation of Detect is fully automatic, no manual calibrations or adjustments are required. The measured signal is analyzed and automatic adjustments are made if required. The device may operate within different conditions in the root canal: dry or wet. Very dry canals should be wetted by hypochlorite or saline solution. Full automation of the apex locator operation simplifies the use and increases the reliability of the measurements. Detect may only be used with stainless steel or nickel titanium endodontic files.

Built-in Demo mode of Detect enables easy simulation of all stages of the treatment and is designed to simplify familiarization of the user with the device.

5.5. **Intended Use:** [807.92(a)(5)]

Detect is an electronic device used to indicate the location of the apex and the working length. This product must only be used in hospital environments, clinics or dental offices, by qualified practitioners.

5.6. **Substantial Equivalence Comparison Table**: [807.92(a)(6)]

Table 5.6: Substantial Equivalence Comparison

Line No.	Device Characteristics	Predicate Device	Candidate Device
		BINGO PRO	**Detect**
1.	Device definition	Electronic apex locator	The same as in BINGO PRO.
2.	Intended Use	Precise apex localization during root canal treatment.	The same as in BINGO PRO.
3.	Indications for use	BINGO PRO is an electronic device used for precise apex localization and working length determination during root canal treatment. The device enables to obtain correct results in canals with different conditions - dry or wet.	Detect is an electronic device used to indicate the location of the apex and the working length. This product must only be used in hospital environments, clinics or dental offices, by qualified practitioners.
4.	Where to be used (clinics, home etc.)	This product must only be used in hospital environments, clinics or dental offices by qualified dental personnel.	The same as in BINGO PRO.
5.	Device category	Active, invasive	The same as in BINGO PRO.

Line No.	Device Characteristics	Predicate Device	Candidate Device
		BINGO PRO	**Detect**
6.	Power Source	Low voltage NiMH rechargeable batteries (2.4V)	The same as in BINGO PRO.
7.	External charger	Input: 120V/50-60Hz Output: 6V DC @ 500mA.	The same as in BINGO PRO.
8.	Current Consumption	Maximum – 250 mA DC.	The same as in BINGO PRO.
9.	Method of calculating location of root canal apex	RMS functions of the measured signals at two frequencies are used to calculate the test scores, which are compared to statistically predefined thresholds.	The same as in BINGO PRO.
10.	Display	3.5" Color TFT Display	The same as in BINGO PRO.
11.	Buttons	Three pushbuttons: 1. On / Off 2. Sound control 3. MODE	Two pushbuttons: 1. On / Off 2. Sound control
12.	Sound indication	Piezzo transducer with sound level control (high, medium, low, mute).	The same as in BINGO PRO.
13.	Adjustment before measurement	Not required	The same as in BINGO PRO.
14.	Calibration	Not required	The same as in BINGO PRO.
15.	Measuring signal amplitude	Nominal – doesn't exceed 25 mV AC.	The same as in BINGO PRO.
16.	Frequencies used for measurements	500 Hz and 8 kHz	The same as in BINGO PRO.
17.	Weight	300 Gr	360 Gr
18.	Dimensions	74 x 120 x 70 mm	80 x 130 x 63 mm
19.	Endodontic Files to be used with the device	BINGO PRO may only be used with stainless steel or nickel titanium endodontic files.	The same as in BINGO PRO.
20.	Type of Connector	The type of connector used – Micro-USB plug.	The type of connector used – IEEE 1394 plug.
21.	Automatic Turn-off function	The device turns off automatically after 5 min. of idle state.	The same as in BINGO PRO.

Line No.	Device Characteristics	Predicate Device BINGO PRO	Candidate Device Detect
22.	Display Zoom Area	Zoom area with the following graphical indications of file tip position: 2.0, 1.9, 1.8, 1.7, 1.6, 1.5, 1.4, 1.3, 1.2, 1.1, 1.0, 0.9, 0.8, 0.7, 0.6, 0.5, 0.4, 0.3, 0.2, 0.1, and 0.0. Additionally file tip position is indicated in numerical form. Over-instrumentation: graphical indication and additional alphanumerical presentation.	Zoom area with the following graphical indications of file tip position: 2.0, 1.9, 1.8, 1.7, 1.6, 1.5, 1.4, 1.3, 1.2, 1.1, 1.0, 0.9, 0.8, 0.7, 0.6, 0.5, 0.4, 0.3, 0.2, 0.1, and 0.0. Additionally file tip position is indicated in numerical form. Graphical indication of over-instrumentation.
23.	Virtual Apex feature	Advanced Virtual Apex with visual and audio feedback.	Virtual Apex feature is not available.
24.	Training mode	DEMO mode is implemented to demonstrate device operation and to shorten learning curve of the user.	The same as in BINGO PRO.

5.7. **Brief discussion of the nonclinical tests** [807.92(b)(1)]

To evaluate the performance of Detect apex locator, ex-vivo test was performed on extracted teeth. The results obtained with Detect were compared to the results of the FDA cleared device - BINGO PRO apex locator. The conclusion of the test was that the apex localization obtained with both devices is the same and that Detect provides clinically acceptable results.

5.8. **Conclusions:** [807.92(b)(3)]

- Detect has the same intended use and fundamental scientific technology as the cleared device – BINGO PRO (K111474).
- Detect was evaluated against the cleared device, and was found to be Substantially Equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 10, 2013

Ms. Yuliya Yutkevich
Quality Assurance & Regulatory Affairs Manager
Forum Engineering Technologies (96) Limited
1 Platin Street, New Industrial Zone
Rishon Lezion, Israel 7565339

Re: K121206
Trade/Device Name: Detect
Regulation Number: Unclassified
Regulation Name: Locator, Root Apex
Regulatory Class: Unclassified
Product Code: LQY
Dated: December 20, 2012
Received: December 20, 2012

Dear Ms. Yukevich:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Forum	Forum Engineering Technologies (96) Ltd.	
Detect 510(k) File	Detect – Indication for Use Statement	Rev. 01
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Section 4: Indication for Use Statement

510(k) Number (if known): N/A K121206

Device Name: Detect

Indications for Use:

Detect is an electronic device used to indicate the location of the apex and the working length. This product must only be used in hospital environments, clinics or dental offices, by qualified practitioners.

Prescription Use √ 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)

Susan Runner DDS, MA 2013.01.10 11:40:34 -05'00'

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

510(k) Number: K121206