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K962803

## 510 ( k ) Notification for Apex Finder Model 7005

### 510 ( k ) Summary

#### Background:

In the practice of dentistry electronic apex locators have been used since 1960 to determine the length of a root canal. This is commonly done by measuring a weak electrical current flowing between two electrodes. The first electrode is a metal probe, for example a reamer or file inserted into the root canal, and the second a metal clip placed on the lip of the patient. Since the impedance between these two electrodes depends on the location of the probe tip within the root canal, the impedance can be used to estimate the location of the probe tip in relation to the apical foramen. The length of the root canal can therefore be obtained by measuring how far the probe is inserted into the canal.

#### The Model 8001 Endo Analyzer:

An apex finder marketed by Analytic Technology received 510 ( k ) clearance in March, 1987 with reference number K864500/A. It is sold under the name Endo Analyzer Model 8001. The Model 8001 is actually a combination apex locator and tooth vitality scanner. Single purpose versions of this instrument are also marketed in different enclosures as Apex Finders Model 7001 and 7002. The subject of this application is an improved version of the model 8001 apex locator..

#### The new Model 7005 Apex Finder:

The new Model 7005 for which 510 ( k ) clearance is sought uses a microprocessor rather than discrete electronic components used in the earlier Model 8001 unit. The new model operates reliably with conductive fluids in the canal, for example sodium hypochlorite. Another advantage is a lower patient current, 3.5 microamperes as compared to 35 microamperes for the Model 8001.

#### Substantial Equivalence Statement:

The Model 7005 is substantially equivalent to two units presently on the market - the ROOT ZX which is marketed by J. Morita USA Inc. and the ENDEX marketed by Osada Electric Co. Both units use patient signals which consist of two sine waves of different frequencies. The ROOT ZX uses 400 and 8000 Hz and the ENDEX uses 1000 and 5000 Hz. Furthermore both devices compare the amplitudes at the two signal frequencies to determine the length of the root canal.

The Model 7005 uses a substantially equivalent approach in that it compares sine waves of different frequencies in the range 500 - 8000 Hz. The patient current level of the Model 7005 is similar to those of the ROOT ZX and the ENDEX. All three units operate from low voltage batteries. The model 7005 uses three AA batteries, the ROOT ZX five AA batteries and the ENDEX rechargeable batteries.

Both the Model 7005 and the ROOT ZX use liquid crystal displays ( LCD ) while the ENDEX uses a meter. The display differences are of minor importance as all three devices have sound annunciation.

The Model 7005 also has a "Condition" indicator not available with either the ROOT ZX or the ENDEX. This indicator displays the conductivity of the root canal and notifies the user of situations where the apex finder might fail to provide an accurate reading. The Model 7005 "Learn" function is the same as the manual calibration method used by the ENDEX.

The Table below compares the Model 7005 with ROOT ZX and the ENDEX. The earlier Model 8001 is also included for completeness.

**EQUIVALENCY COMPARISON TABLE**

	<b><u>Model 7005</u></b>	<b><u>ROOT ZX</u></b>	<b><u>ENDEX</u></b>	<b><u>Model 8001</u></b>
<b>Patient Current</b>	3.5 $\mu$ A	< 10 $\mu$ A	2 $\mu$ A	35 $\mu$ A
<b>Frequencies</b>	500-8kHz	400, 8kHz	1kHz, 5kHz	20 kHz
<b>Batteries</b>	3 size AA	5 size AA	Rechg.	4 size AA
<b>Display</b>	LCD	LCD	Meter	LED
<b>Sound</b>	Yes	Yes	Yes	Yes