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Section III - 510(k) Summary of Safety and Effectiveness

Submitter:

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Device Name:

- Trade Name - Touch n' Heat
- Common Name - Dental Instrument Heater
- Classification Name - Pulp Tester, per 21 CFR § 872.1720

Devices for Which Substantial Equivalence is Claimed:

- Union Broach, a division of Moyco Industries, Inc., Odontotest Thermal Pulp Tester

Device Description:

The device, which is battery-operated (Model 5001 and 5004) or powered by a wall adapter (Model 5002), is designed to provide continuous heat at the tip of a dental instrument, the Hot Pulp Test Tip, to test tooth response to thermal stimulus. The battery operated models are fully rechargeable through the use of the plug-in charge adapter. The Hot Pulp Test Tip is heated to the desired temperature. A medium, such as a ball of softened gutta percha, is used to transfer the heat from the Hot Pulp Test Tip to the tooth. The gutta percha ball is dipped into talcum powder or Vaseline to prevent it from sticking to the tooth. The Hot Pulp Test Tip is placed in firm contact with the tooth, ensuring that a good contact is established. The patient's response to the heat is evaluated by the clinician to determine whether the pulp is healthy or inflamed.

Intended Use of the Device:

The intended use of the device is to provide continuous heat at the tip of a dental instrument, the Hot Pulp Test Tip, to test tooth response to thermal stimulus.

Substantial Equivalence:

The device is substantially equivalent to other legally marketed devices in the United States. The thermal pulp tester marketed by Union Broach, a division of Moyco Industries, Inc., is intended for the same use as the product manufactured by Analytic Technology Corporation.