

## Memorandum



**To:** Intertek **Date:** 05/27/2011

**From:** Andreas Sand **c.c.:**



**Subject:** Changes to FCC ID: YTESM03 since original filing

This memo is intended to summarize the changes made to FCC ID: YTESM03 since the original filing. Items not listed are considered no change.

### BTE

	<u>SoundBite (2010)</u>	<u>Modified SoundBite (2011)</u>
<b>Mechanical design</b>		
Material: - Housing, enclosure	Polyetherimide GE Plastics ULTEM HU 1000 Cleared as a patient contacting material in dental and other medical devices (e.g. K014050, K031133, K077534, and K072394) USP class VI Certified	Polyetherimide GE Plastics (Sabic) ULTEM HU 1010 According to the material certification from the supplier the material pass the requirements outlined by ISO10993 for cytotoxicity, irritation and sensitization USP class VI Certified
Material: - Housing, connector / stress relief	Polyetherimide GE Plastics ULTEM HU 1000 Cleared as a patient contacting material in dental and other medical devices (e.g. K014050, K031133, K077534, and K072394) USP class VI Certified	GE Plastics (Sabic) Lexan HP 1 According to the material certification from the supplier the material pass the requirements outlined by ISO10993 for cytotoxicity, irritation and sensitization USP class VI Certified
Material: - Microphone Tubing	Pebax 7233 Cleared as patient contacting	Pebax 7233 Cleared as patient contacting

	material for cardiovascular catheters (e.g. K042553, K052004, K080988) USP class VI Certified	material for cardiovascular catheters (e.g. K042553, K052004, K080988) USP class VI Certified
Material: - Housing, microphone	Polyetherimide GE Plastics ULTEM HU 1000 Cleared as a patient contacting material in dental and other medical devices (e.g. K014050, K031133, K077534, and K072394) USP class VI Certified	Polietherimide GE Plastics (Sabic) ULTEM HU 1010 According to the material certification from the supplier the material pass the requirements outlined by ISO10993 for cytotoxicity, irritation and sensitization USP class VI Certified
Material: - Electrical contacts	Gold plated pin Cleared for breached skin surface (K091055, K091721, K032951)	Gold plated pin Cleared for breached skin surface (K091055, K091721, K032951)
Material: - Ear dome/plug	Commercially available	Silicone LSR (liquid silicone rubber) Cleared for urology (K915571, K970855, K045182, K080007)
Material: - Adhesive	Loctite M-121 HP Epoxy Adhesive USP class VI certified	Loctite M-121 HP Epoxy Adhesive USP class VI certified
<b>Electrical Design</b>		
Electronic Design: - Flammability grade	UL-94 V0	UL-94 V0
Electrical design: - Radio	On-Semi SA3291 hybrid including NXP NxH2180 radio.  Operating frequency: 10.6MHz Modulation scheme: CPFSK	On-Semi SA3410 hybrid including NXP NxH2180 radio.  Operating frequency: 10.6MHz Modulation scheme: CPFSK
Electrical design: - Battery operated	Internally powered: 1x Single cell Lithium-ion Polymer: Lishen PP031012AB Capacity: 19mAh	Internally powered: 2x Single cell Lithium-ion Polymer: Lishen PP031012AB Capacity: 2x 19mAh
Electrical design: - Battery short / over current circuit protection	N/A	Seiko Instruments S-8211CAZ-I6T1G
Electrical design: - Battery charger	Linear Technology LTC4065L	Linear Technology LTC4065L

Electrical design: - Voltages	4.225V maximum voltage	4.225V maximum voltage
Electronic design: - Charge terminal leakage	1.35V, 19uA	1.25V, 8uA
<b>Antennas</b>		
Antennas: - Dimensions	Custom rod approximately: L15.9mm x D2.42mm	Rod: L15mm x D2mm
Antennas: - Inductance	3.8uH	3.8uH
Antennas: - Core material	FairRite material 67	FairRite material 61

### System labeling

	<u><b>SoundBite (2010)</b></u>	<u><b>Modified SoundBite (2011)</b></u>
6 Identification		
6.1 External marking	Laser printed polyester label; encapsulated polyester label	Pad printed ink, laminated polyester labels, laser etching
6.1.2 BTE label	