

K970418

**Premarket Notification [510(k)] Summary**

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**Trade name:** PMT® Anchor Bolt, Accessory Depthalon® Depth Electrode

**Common name:** Anchor Bolt

**Classification name:** No known classification name.

**Equivalent device(s):**

The PMT Depth Electrode Anchor Bolt is equivalent to the Smith Skull Anchor bolt manufactured by Ad-tech Medical Instrument Corporation.

**Device Description**

**Basic Design**

The PMT Depth Electrode Anchor Bolt is an accessory used in cases where it's necessary to minimize concerns about potential cerebrospinal fluid (CSF) leakage and infection of the subdural space while stabilizing the electrode during intraoperative electroclinical characterization.

The PMT Depth Electrode Anchor Bolt is attached onto the skulls with the insertion of the Anchor Bolt Tapered Screw Threads into a pre-drilled burr hole, through a skin incision.

Once installed on to the skull a PMT Depthalon® Depth Electrode (510(k) number K802151 and K802152) can be inserted into the Anchor Bolt Screw Cap Port Hole through the Silicone Gasket and into the cranium. The PMT Depth Electrode Anchor Bolt is made of Titanium alloy (Ti 6Al 4V) with a silicone gasket. The gasket is designed to accept the PMT Depthalon® Depth Electrode.

The port hole of the PMT Depth Electrode Anchor Bolt is designed to accommodate depth electrodes with a diameter of  $0.050 \pm .005$  inches. Additional designs will be made available to accommodate different manufactures and models of Depth Electrodes with various diameters.

Once the Depth Electrode is at the intended foci, the Port Hole Screw Cap can be tightened to fixture the PMT Depthalon® Depth Electrode . The Device is designed to withstand a longitudinal ( push/ pull)100 gram force.

The PMT Depth Electrode Anchor Bolt is available in 25mm, 30mm, 35mm and 40mm lengths to accommodate neurophysiologist preference.

The PMT Depth Electrode Anchor Bolt is provided in a primary and secondary pouch. The pouch is a Tyvek and cellophane configuration. The Tyvek pouch with the chevron design feature provides a 1- 3 lb. pull apart strength.

The PMT Depth Electrode Anchor Bolt is provided sterile or non-sterile. The type of sterilization used is 100% Ethylene Oxide. The sterilization method employed is the overkill method and validated to the terminal process endpoint probability of a non-sterile unit of  $10^{-6}$ .

The PMT Depth Electrode Anchor Bolt is provided pyrogen free. The method of determination is the Limulus Amebocyte Lysate Test. The Bacterial Endotoxin test is conducted as described in the USP Endotoxin Reference Standard. The pyrogen limit for the PMT Depth Electrode Anchor Bolt is 2.4 Eu/device.

The PMT Depthalon® Electrode Anchor Bolt is tested for biocompatibility. The silicone gasket material has been tested per the General Program Memo # G95-1, the device is classified as an implant device, contacting tissue/ bone with an "A" class duration of contact (< 24 hours). The silicone materials used passed the tests for Cytotoxicity, Sensitization, Irritation and Acute Systemic toxicity. The Titanium alloy has passed the Intracutaneous, Acute Systemic Toxicity and Sensitization test (Implant).