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Premarket Notification [510(k)] Summary

Submitters name: PMT CORPORATION

Submitters Address: 1500 Park Road
Chanhassen, MN 55317

Phone: (612) 470-0866

Fax: (612) 470-0865

Contact name: Edward F. Valdez

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Trade name: PMT Cortac Cortical Electrode

Common name: Cortical Electrode

Classification name: Electrode, Cortical (per 21 CFR section 882.1310)

Equivalent device(s):

The Ojemann Cortical Stimulator(OCS -1), manufactured by Radionics, Inc. The Wyler Subdural Strip Electrode, manufactured by ADTEC and the PMT 2111-4 stainless steel Cortac Cortical electrode has met the criteria for substantial equivalence to the series of PMT Cortac cortical electrodes.

Device Description:

The Cortac Cortical Electrode is used intraoperatively for monitoring recordable electrical brain activity or Electroencephalography (EEG) when less invasive methods do not provide the electrophysiology data necessary. This invasive intracranial, subdural electrode recording is performed directly on the surgically exposed brain. This method is necessary when the seizure focus is to small and or to deep within the brain to produce a recordable EEG seizure. The Cortac Cortical Subdural strip and grid electrode are used in cases where it's necessary to establish a high degree of confidence in the electrical localization (Foci), seizure frequency, severity type and other electroclincal characteristics.

The Cortac Cortical Electrode Subdural strips and subdural electrode grids are inserted subdura onto the gray matter of the brain through a skin incision and bone flap (Craniotomy). The number of electrode contacts required in the subdural strips and grid increases for wide spread coverage. PMT offers cortical electrodes with 1 upto 64 electrodes.

Once on the brain the subdural strips and subdural electrode grids must be pliable so that it lies over the features of the brain, such as specific gyral convolutions, lesions and brain anatomical topography. The strips or grids envelop the electrodes, except for the exposed electrode contact. The strips and grids are manufactured with a biocompatible silicone with a thickness and durameter enabling pliability of the strip or grid to conform to the brain and its anatomical topography without the hazard of buckling and compression of the cortical veins and the cortex.

The electrodes are either stainless steel or platinum metal. The stainless steel and platinum electrode contact and wiring system are preferred for the electroconductivity and biocompatibility with minimal resistance to electrolysis. The electrophysiologist may prefer one material choice over another knowing the electrical resistance of the stainless steel is higher than that of platinum.

The electrode contacts are die and punch cut by design into a top hat shape . The top hat shape allows the reading portion of the electrode contact surface approximately level with the silicone strip and grid while allowing sufficient embedded electrode contact area to maintain integrity of the structure. The benefit of the design allows for maximum contact with the brain tissue thus minimizing pockets or space available for insulating barriers such as, air or cerebrospinal fluid (CSF). The electrode contacts are available in three sizes to accommodate the variety of patients and electrophysiologist preference.

The electrode contacts are attached to the conducting wire (same material type) with a weld. The wire is insulated to prevent wire from shorting with other wires in the assembly. The weld provides good electrical continuity with minimal electrical resistance across the contact to wire transition,while providing a tensile strength comparable to that of the wire.

A variety of wiring patterns are available to minimize wire to wire contact for the different number of electrode contacts.

The wires converge into silicone tubing conduit that provides the mechanical structure between the Inplanted strip or grid and the connector assembly (external). The silicone tubing is sealed into the proximal end of the strip or grid. A maximum of 10 wires are in each lumen of the bilumen tube. The 64 contact electrode will have no more than 4 standard bilumen tubes attached.

The silicone tubing conduit terminates in a connector. The connector attaches the silicone tubing and wire. The wire and connector contacts are press fit. Silicone adhesive is used to attach the silicone tubing to the connector.

Several types of connectors are available. As the number of electrode contacts increase, the tube conduit may become so bulky that skin incisions and passage through the subcutaneous tissue becomes necessary to minimize concerns about potential cerebrospinal fluid (CSF) leakage and infection of the subdural space. The mini-connector has a 6 mm diameter and can be brought out through the skin using guiding needle punctures. Larger connectors are available.

The connector connects to the interconnect cable external of the patient. The interconnect cable attaches to the EEG equipment. The connector contacts are brass female connector pins.

The PMT Cortac Cortical Electrode 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 Cortac Cortical Electrode is provided sterile or nonsterile. The type of sterilization is 100% Ethylene Oxide. The sterilization method employed is the overkill method and validated to the terminal process endpoint probability of a nonsterile unit of 10^{-6}.

The PMT Cortac Cortical Electrode 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 Cortac Cortical Electrode is 2.4 Eu/device.

The PMT Cortac Cortical Electrode is tested for biocompatibility 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 Cortac Cortical Electrode passed the tests for Cytotoxicity, Sensitization, Irritation and Systemic toxicity.