

K962928

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**PREMARKET NOTIFICATION
510(k) SUMMARY**

1. SUBMITTER:

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2. DEVICE NAME:

- Trade Name:
 - a. Micro-Ventricular Pressure-Temperature Monitoring Kit (110-4HMT)
Parenchymal Pressure-Temperature Monitoring Kit (110-4BT)
 - b. Multi-Parameter Monitor (MPM)
- Common Name:
 - a. Intracranial Pressure and Temperature Monitoring Kit
 - b. Multi-Parameter Monitor
- Classification Name:
 - a. Intracranial Pressure Monitoring System
 - b. Intracranial Pressure Monitoring System

3. PREDICATE DEVICE:

Camino NeuroCare™ Intracranial Pressure-Temperature Monitoring Kit:

Model 110-4BT is equivalent to:

Camino, Intracranial Pressure Monitoring Kit, Model 070, 853864C
Electromedics, Inc., Esophageal, Rectal, Nasopharyngeal Probe, Model 2403, K813459A.

Model 110-4HMT is equivalent to:

Camino, Micro Ventricular Pressure Monitoring Kit, Model 110-HM, K914735
Electromedics, Inc., Esophageal, Rectal, Nasopharyngeal Probe, Model 2403, K813459A.

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3. PREDICATE DEVICE:

Camino NeuroCare™ Multi Parameter Monitor:

Model MPM is equivalent to:

Camino, Direct Pressure Monitor, Model V420, K893232
SpaceLabs, Patient Monitor, Model Alpha PC Patient Computer,
K842616.

4. DEVICE DESCRIPTION:

The Intracranial Pressure-Temperature Monitoring System consists of a catheter and monitor. The catheter is a sterile transducer-tipped pressure monitoring catheter with thermistor and accessory items to be used as a diagnostic tool for rapidly determining and continuously monitoring intracranial pressure and temperature. The Camino catheter has a miniature transducer and thermistor at the distal tip. The pressure transducer is identical to the Camino predicate device. The design eliminates the need for a "fluid-filled system" to carry pressure waves to an external transducer. The transducer is 4F, fiber optic with a pressure measurement range of -10 to 250 mmHg and a temperature measurement range of 30°C -40°C.

The Multi-Parameter Monitor (MPM) is a compact, portable device for use with Camino Pressure-Temperature catheters. The MPM measures Intracranial Pressure (ICP), Intracranial Temperature (ICT) and calculates Cerebral Perfusion Pressure (CPP). The MPM provides a continuous display of the pressure waveform, as well as mean ICP, CPP, temperature or systolic and diastolic values. A continuous record of mean pressure and temperature values over the most recent 24-hour period is stored in memory, and can be displayed on command as a TREND either as the most recent 8 or 24 hour period. An analog output accessory provides a continuous ICP waveform for hard copy documentation or data acquisition. Although the MPM is intended to be a stand alone system, it also conveniently connects to any hospital bedside monitoring system. A built-in rechargeable battery permits monitoring during patient transport. The monitor is equipped with an high ICP alarm. The dimensions are 274 mm x 216 mm x 89 mm and weighs 4.3 Kg.

5. INTENDED USE:

Model 110-4BT:

Use by a qualified neurosurgeon for direct measurement of intracranial pressure and temperature in the parenchyma.

Model 110-4HMT:

Use by a qualified neurosurgeon for direct measurement of intracranial pressure and temperature in the ventricles and cerebrospinal fluid drainage.

Intended to be used with an external drainage system as indicated by individual manufacturers.

6. SUBSTANTIAL EQUIVALENCE:

Pressure:

The ICP/T catheter and monitor have the same indication statements for monitoring pressure as Camino's predicate devices.

Temperature:

Predicate temperature-sensing devices include the Electromedics, Model 2403, Temperature Probe, K813459A. The predicate probes are used to measure the temperature of a target organ or tissue. Camino's temperature probe has the same use.

Nevertheless, the ICP/T has a difference in the indication statements in regard to temperature. The difference refers to the tissue in which the temperature is taken. For example, the Electromedics predicate catheter is labeled for general temperature use. Other indications include general surgery, cardiovascular surgery, anesthesiology, critical care, newborn care, and neonatal care. The Camino probes have similar labeling in that they are for general uses that may include surgery, critical care, pediatric care and head injured patients. The Electromedics probe is labeled to take a patient's temperature in the esophagus, on the skin surface, in cardioplegia systems and in the myocardium. The Camino pressure-temperature probe is labeled to be used in the brain, with either parenchyma or ventricular placement.

Monitor:

The ICP/T monitor and both predicate monitors display pressure.

The ICP/T monitor and SpaceLabs monitor display temperature.

The ICP/T monitor and SpaceLabs monitor display Cerebral Perfusion Pressure (CPP).

The ICP/T monitor and both predicate monitors display a waveform.

The ICP/T monitor and both predicate monitors display trends.

The ICP/T monitor and both predicate monitors comply with UL Medical Equipment standards.

The ICP/T monitor and the predicate monitors comply with AAMI/ANSI Safe Current Limits standards.

7. PERFORMANCE TESTING:

Camino NeuroCare conducted animal studies to support substantial equivalence. We conducted a comparative study of the subject (test) device measuring intracranial temperature compared with a predicate device, located along side the test device, also measuring intracranial temperature over a varied temperature range. The temperature measurements were $\pm 0.4^{\circ}\text{C}$ between the test device and predicate device in the 10 animals tested. These data support the claim of substantial equivalence.

8. CONCLUSIONS

The contact area of the Camino probe is of the same design, has the same materials, and it is inserted into the body in the same manner as predicate Camino probes. Thus, the questions of safety are the same. The diagnostic effect of temperature probes for general use is to provide temperature information to a physician for whatever use he or she may choose, based on the user's training and experience. The effectiveness of a temperature probe for diagnostic or monitoring use is determined by its ability to deliver an accurate temperature reading. This is the same standard that was used for predicate devices, some of which were cleared for organs and tissues which may have been different from those for which existing predicate devices were cleared.

Based on the above information Camino NeuroCare™ Inc., concludes that the ICP/T Monitoring system demonstrates substantial equivalence to the predicate devices.