EBI Electro Biology

Enhancing Bone Healing through Applied Science

SEP 27 [redacted]

K963261

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS FOR THE EBI THERMAL THERAPY SYSTEM

Date Prepared: August 19, 1996

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The EBI Thermal Therapy System is intended to apply localized cold or heat therapy to body surfaces. The EBI Thermal Therapy System is designed to lower or raise the surface skin temperature by delivering water at a controlled temperature to the target site via a thermal pad. The system is designed for repeated uses in the hospital or home. The thermal pad is designed for single patient use. (Water Circulating Hot or Cold Pack Devices have been recommended by the Physical Medicine Panel for classification into Class II under 21 CFR 890.5720).

The EBI Thermal Therapy System consists of a water delivery system, insulated hoses and a thermal pad. The water delivery system includes the following components: case, water pump, fan, water reservoir, thermal exchangers, electronic control module, display, and keypad. The EBI Thermal Therapy System operates on standard house current. A variety of pads, in different shapes and sizes, are available to accommodate different anatomical sites. Both sterile and nonsterile pads are available for use with the EBI Thermal Therapy System. The EBI Thermal Therapy System is substantially equivalent* to the Danninger Thermal-Max Thermal Therapy Unit and the InCare Hot/Ice System.

Comparative testing was performed on the EBI Thermal Therapy System and the Danninger Thermal-Max Thermal Therapy Unit. The performance testing demonstrates that the systems have equivalent performance characteristics.

In conclusion, the performance testing as well as the comparison of the systems' intended uses, designs and components demonstrate that the EBI Thermal Therapy System is substantially equivalent to the Danninger Thermal-Max Thermal Therapy Unit and the InCare Hot/Ice System 3.

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* Any statement made in conjunction with this submission regarding a determination of substantial equivalence to any other product is intended only to relate to whether the product can be lawfully marketed without pre-market approval or reclassification and is not intended to be interpreted as an admission or any other type of evidence in patent infringement litigation. [Establishment Registration and Premarket Notification Procedures, Final Regulation, Preamble, August 23, 1977 42 FR 42520 (Docket No 76N-0355)]

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