

K961809

FEB 26 1997

APPENDIX "E"  
510 (k) Summary

In accordance with 21 C.F.R.807.92, the following information constitutes MEDI Consultants, Inc. summary for the She-Li TENS(TM) Model No. 101-Rx:

MEDI Consultants, Inc. has demonstrated that its She-Li TENS(TM) Model No. 101-Rx is substantially equivalent to the Electreat TENS device, manufactured by the Electreat Inc. of Minneapolis, Minnesota. Since the Electreat was manufactured since prior to 1920, it was grandfathered as of May 28, 1976 and produced continuously till the summer of 1993.

The She-Li TENS(TM) utilizes the same solenoid coil and interrupter assembly which is at the heart of the Electreat device. Shrouded receptacles are utilized in the She-Li TENS(TM), as recommended by the Agency. Two Alkaline "C" cell batteries are used in a more up to date mechanical package. The Electrical output of the She-Li TENS(TM) is identical to that of the former Electreat. However, the She-Li TENS(TM) provides safer, shrouded output receptacles for the single channel (just as in the original Electreat device).

The She-Li TENS(TM) device is indicated for reducing the symptoms of:

- A. Chronic Intractable Pain, and
- B. Post Traumatic Acute Pain

by placing contacts on the body per instructions by Dr. C.N. Shealy, M.D., Ph.D. for the type of pain encountered. Suitable instructions are included in the Professional Instruction Manual.

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Date: May 9, 1996