K955736

510(k) Notification for Stim-8: Appendix IX

510(k) Summary of Safety and Effectiveness

This summary is submitted in compliance with the FDA interim rule 21 CFR 807.92.

(a) (1) Submitted by:

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(2) Trade name of device: Stim-8

Common name: Muscle Stimulator

Classification name: Powered muscle stimulator; §890.5850

(3) Identification of predicate or legally marketed device: NeuroTech-16 Program System Controller Model 280
(NeuroTech Inc., 510(k) # K860315)

166

510(k) Notification for Stim-8: Appendix IX

(4) Description of device:

The Stim-8 is a compact, battery powered muscle stimulator. It is used to repetitively contract skeletal muscles by providing transcutaneous electrical pulses to areas of the body that require therapy for the indicated medical conditions. The parameters of the Stim-8 cannot be set by the user. Four channels are available on the Stim-8. Each channel operates independently and if desired one, two, three or four channels may be used simultaneously. The only controllable parameters are the amplitude intensity controls of the stimulation.

(5) Intended uses:

The Stim-8 is used for stimulation of muscles for the purposes of relaxation of muscle spasms, prevention or retardation of disuse atrophy, increasing local blood circulation, muscle re-education, immediate post-surgical stimulation of calf muscles to prevent venous thrombosis and maintaining or increasing range of motion.

These uses are similar to the predicate marketed device identified in section (3) of this summary.

(6) Technological comparison

The Stim-8 is similar the NeuroTech-16 Program System Controller in that both utilize microprocessor controlled stimulation parameters. Output for either device is suitable for muscle stimulation using standard skin surface electrodes. Both devices are similar in basic operational design and use the impedance of the output transformer to achieve a near net zero charge into the skin. The Stim-8 is effectively a more limited, portable version of the NeuroTech-16 Program System Controller with a replaceable battery.

167

510(k) Notification for Stim-8: Appendix IX

(b) (1) Non-clinical tests:

Comparisons of stimulation outputs for the Stim-8 and the predicate NeuroTech-16 Program System Controller show similar results that are suitable for muscle stimulation. To minimize potential electrical and mechanical hazards, BMR adheres to recognised and established industry practice and all devices are subject to final performance testing. The Stim-8 is designed and tested to EN 60601-1-2 (IEC 601-1-2).

(2) Clinical tests:

No clinical testing was performed.

(3) Test conclusions:

Testing of the stimulation output parameters of the Stim-8 indicate that the device is safe, that it provides appropriate stimulation output for effective muscle stimulation and that it performs as well as or better than the legally marketed predicate device identified in section (3) of this Summary.