

XI. SAFE MEDICAL DEVICES ACT OF 1990 SUMMARY OF SAFETY AND EFFECTIVENESS.

March 20, 1996

A. Submitter: Dr. Mark Friedman, 660 Gramatan Ave., Mt. Vernon, NY.

I. Classification Names and numbers:

Hot or cold pack, water-circulating, 89ILO*
Cold pack, reusable, 89IME

K955529

II. Common/Usual Names: Cold Pack

JUN 10 1996

III. Proprietary Names: Cryotron™ Cold Probe

IV. Establishment Registration Number: In process

V. Classification: Circulating water cold packs have been classified in the Code of Federal Regulations, in class II, CFR 890.5720 by the Physical Medicine Panel, and placed in Tier II by the Office of Device Evaluation

VI. Performance Standard: None established under section 514.

VII. Description of the Device: Cryotron is fabricated by joining two hollow metal or plastic tubes together into a hollow metal tip which is shaped to fit over the maxillary nerve section or other area selected for cold therapy. Ice water driven by a small pump enters the smaller tube and exits the large tube, chilling the metal which is covered by a disposable plastic sheath. The product will be sold non-sterile; prepackaged, presterilized plastic sleeves will be provided with the Cryotron.

VIII. Labels of the product and competitive devices are provided.

IX. Substantial Equivalence Statement. The "510(k) "Substantial Equivalence" Decision-Making Process (Detailed) from ODE Guidance Memorandum #86-3 was followed as described below:

1. These products have the same intended use, to cool a small portion of the body to provide temporary relief of minor aches and pains and muscle spasms or bruises. These are the same as those of the predicate devices. These products also have the same intended uses as similar products currently cleared for marketing by the 510(k) process, and several that are exempt (CFR 890.5700) that are exempt from 510(k) requirements.
2. The technological characteristics for this product are the same as those for the predicate devices and those currently on the market. The Cryotron probe is a common reusable type, made of chrome-plated brass and is sold non-sterile. The pump, cooler, and tubing are of plastic similar to that used in equivalent products. The plastic cover is disposable and is sold packaged separately.
3. Descriptive information provided shows that the materials from which the Cryotron device are made is substantially equivalent to (nearly identical with) those of similar products, used for identical purposes, currently on the market.

000009

3. Predicate devices

This device is substantially equivalent to preamendment devices classified as shown above. Specifically, the Cryotron device for which we are seeking marketing clearance is described in item 1. However, variations of this device, used in this office for the same purpose include an ice-extrusion pack which could be considered as an item 2 product, exempt from 510(k) requirements.

The device also is substantially equivalent to devices currently on the market such those sold by Kinetic Concepts, Inc. K-891152 and K-891151; Seabrook Medical Systems, K-902269; Breg, Inc., K-920581, K-914434; Toronto Medical Corp., K-935841; Electro-Biology, Inc., K-945067 and others. Labels and labeling for the Seabrook Medical Systems, Electri-Cool as well as for simpler systems such as EBice by Electron Biology, Inc. and DeltaTherm by DeltaTherm, Inc. (to which the Cryotron is most similar) are shown for comparison in Attachment III. The device is also very similar to Hollister's System 3 (K-915196).

4. Descriptive information provided shows that the materials from which the Cryotron device are made is substantially equivalent to (nearly identical with) those of similar products, used for identical purposes, currently on the market.

End of Summary