

K961857

JUL - 3 1996

EXHIBIT #1  
Page 1 of 2

510(K) SUMMARY

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 assigned 510(k) number is: K961857.

1. Submitter's Identification:

Ms. Carol Bergh  
VP Regulatory Affairs  
Graham-Field, Inc.  
400 Rabro Drive East  
Hauppauge, NY 11788

Date Summary Prepared: May 6, 1996

2. Name of the Device:

Labtron Electromax Electronic Stethoscope

3. Predicate Device Information:

Littmann Brand Electronic Stethoscope  
510(k) #K771653, 3M Company, St. Paul, Minnesota

4. Device Description:

This electronic stethoscope electronically amplifies sound with fingertip control; it is turned on by pressing and holding a button on the back of the diaphragm housing. The stethoscope has a volume control and a two position frequency response switch.

5. Intended Use:

For projecting the sounds associated with the heart, arteries, veins and other internal organs, using the principles of electronic amplification to enhance the acoustical sounds of the device.

6. Comparison to Predicate Devices:

Basic design is comparable in both operation and functionality, with the following differences: the Labtron electronically amplifies sound; the Littmann uses 2 silver oxide batteries vs. the Labtron utilizing 4 alkaline manganese batteries, frequency ranges for the Littmann is 20-200 Hz; the Labtron has an electrostatic microphone and only the Littmann has speaker in tubing vs. both having electronics in the chest piece.

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Testing information demonstrating safety and effectiveness of the Labtron Electromax device in the intended environment of use is supported by testing conducted in accordance with FDA's guidelines "Reviewer Guidance for PMN Submissions", DCRND outlining electrical, mechanical and environmental performance standards.

8. Discussion of Clinical Tests Performed:

Non-Applicable

9. Conclusions:

Based upon the aforementioned information, the Labtron Electromax Electronic Stethoscope is substantially equivalent to the 3H Littmann Brand Electronic Stethoscope, and, safety and effectiveness have been established.