2/18/99

XII. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS (Separate Page)

K980689

A. Submitter: Frank Friddle, Jr., Friddle's Orthopedic Appliances, Inc., 12306 Belton Honea Path Hwy, Honea Path, SC, 29654

I. Classification: Class II.

II. Common or usual name: Halo traction or immobilization system,

III. Proprietary Name: Friddle's Halo System™

IV. Registration No.: 1053709

V. Classification Name: Cranial Skull Tongs, 84HAX, CFR 882.5960, Class II.

VI. Performance standards: None. Titanium alloy meets ASTM specifications.

VII. Description:

The Friddle Halo system is very similar to several halo systems, which are designed to hold the skull firmly in place relative to the torso so that the cervical vertabrae are immobolized after surgery or injury. The system is comprised of a ring, rods, and braces system made of a carbon fiber-epoxy composite which is placed over a vest made of high-density polyethylene, lined with Kodel or sometimes sheepskin. The skull pins are made of CP titanium. The titanium skull pins, carbon fiber-epoxy composite rods, high-density polyethylene, Kodel, and sheepskin are used throughout the industry.

VIII. Labels and Labeling: Labels and Instructions for Use are provided. Competitive labels and labeling are provided.

IX. Indications for Use: To provide traction/immobilize a patient with a cervical spine injury (fracture or dislocation)

X. Substantial Equivalence:

The Friddle Halo System is substantially equivalent to the classified device and to other devices cleared for marketing by the 510(k) process such as the "Halo Traction Cervical Immobilizer" (K822885), "Bremer Imaging Tongs, MRI model" (K924506), "Ace Cervical Traction Halozs, Tongs, and Pins," (K954069), the "Halo Ring" (K930153), and is most similar to the PMT Halo/Orthopedic Jacket System (K834047). Several of these products are listed below for convenient reference. The "510(k) Substantial Equivalence Decision-making Process (Detailed) from ODE Guidance Memorandum #86-3 was followed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 18 1999

Mr. Frank E. Friddle, Jr.
President
Friddle's Orthopedic Appliances
12306 Belton-Honea Path Highway
P.O. Box 207
Honea Path, South Carolina 29654

Re: K980689
Trade Name: Friddle Halo System™
Regulatory Class: II
Product Code: HAX
Dated: January 20, 1999
Received: January 21, 1999

Dear Mr. Friddle:

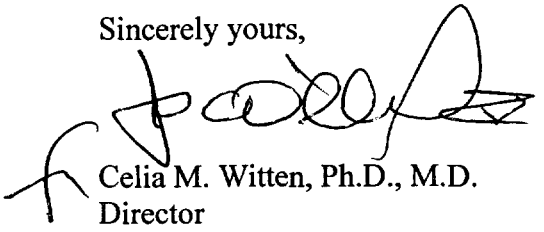
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

IX. Indications for Use: [Separate Page]

510(k) Number: K980689

Device Name: Friddle Halo System™.

Indications for Use: This device is designed to provide traction and/or to immobilize a patient with a cervical spine injury or after surgery.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K980689

Prescription Use ✓
(Per 21 CFR 801.109)

Over The Counter Use

(Optional Format 1-2-96)