K031195

OCT 1 0 2003

EXHIBIT 2

251 Seneca Street
Buffalo, New York USA 14204-2088
Voice: 716-842-4000
Toll-Free: 1-800-521-1022
Fax: 716-842-4040
E-mail: info@ethoxcorp.com
Contact: Dodi Kingsfield
Quality Systems and Regulatory Affairs Manager

510(k) Summary

1. Identification of the Device:
   Proprietary-Trade Name: Ethox CUF-COVER™
   Classification Name: Blood pressure cuff, Product Code: DXQ
   Common/Usual Name: Blood pressure cuff cover.

2. Equivalent legally marketed device: CUFF GUARD, BOWEN MEDICAL SERVICES, INC. K952825

3. Indications for Use (intended use). This device is intended to reduce or prevent patient to patient cross contamination which can occur during blood pressure measurement procedures, for single patient use only. Covers a blood pressure cuff to provide a barrier between patient and cuff..

4. Description of the Device: This device is a cover for blood pressure cuffs. It is made non-woven polypropylene with a polyethylene coating. Blood pressure cuffs are used throughout the healthcare industry as a means of monitoring patient blood pressure. Because blood pressure cuffs are used on multiple patients there is a concern about cross contamination. When the blood pressure cuffs become contaminated they should be cleaned. A blood pressure cuff cover can reduce the need to clean blood pressure cuffs.

   In order to address the cross contamination issue for blood pressure cuffs a blood pressure cuff cover has been designed. The product is a non-sterile, clean, ready to use sleeve that covers a blood pressure cuff. The cuff cover has the potential to reduce transfer of patient contamination to the cuff and from the cuff to the patient.

   The blood pressure cuff cover is a single patient product designed to survive average use during an average hospital stay. If the blood pressure cuff cover becomes contaminated, soiled or torn during this time it would be replaced with a new blood pressure cuff cover.

5. Safety and Effectiveness, comparison to predicate device:

Element of Comparison	Bowen Medical Cuff-Guard K952825	Ethox CUF-COVER™
Intended Use	This device is has the potential to reduce or prevent patient to patient cross contamination which can occur during blood pressure measurement procedures. Covers a blood pressure cuff to provide a barrier between patient and cuff. (reusable (cleanable).	SAME except for single patient use only
Materials	White spun plastic and Velcro closure	Thin non-woven polypropylene with a polyethylene coated inner layer. The sheet is folded over and the inner poly layer welded together along each end. Velcro closure.
Sizes	Six sizes: Newborn, Infant, Child, Adult, Large Adult, Thigh	Small, Medium, Large
Closure	Two sided adhesive tape with removable liner	Zip-Lock
Cover material	Opaque	Translucent

6. Conclusion: In all respects, the Ethox CUF-COVERs™ are substantially equivalent to Bowen Medical Cuff-Guard. The covers are made of similar materials. Laboratory testing shows the material is an effective microbial and air barrier. Clinical testing shows the cover does not significantly affect blood pressure readings.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 0 2003

Ethox Corp.
c/o Mr. Daniel Kamm
Regulatory Engineer
Kamm & Associates
P.O. Box 7007
Deerfield, IL 60015

Re: K031195
Trade Name: Cuf-Cover™
Regulation Number: 21 CFR §870.1120
Regulation Name: Blood-Pressure Cuff
Regulatory Class: Class II (two)
Product Code: DXQ
Dated: September 2, 2003
Received: September 5, 2003

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4646. 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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

j) Indications for Use

510(k) Number_____

Device Name: CUF-COVER™
This device has the potential to reduce or prevent patient to patient cross contamination which can occur during blood pressure measurement procedures, for single patient use only. Covers a blood pressure cuff to provide a barrier between patient and cuff.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over the Counter Use_____
(Per 21 CFR 801.109)

for BDZ
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K031195