April 26, 2022

D. E. Hokanson, Inc.
Eugene Hokanson
12840 N.E. 21st Place
Bellevue, WA 98005-1910

Re: K932851
Trade/Device Name: Disposable Penile Blood Pressure Cuffs
Regulation Number: 21 CFR§ 870.1120
Regulation Name: Blood pressure cuff
Regulatory Class: II
Product Code: DXQ, DXN

Dear Eugene Hokanson:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated November 15, 1993. Specifically, FDA is updating this SE Letter because FDA has better categorized your device technology under product code DXQ.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Mark Antonino, OHT3: Office of GastroRenal, Ob-Gyn, General Hospital and Urology Devices, (240) 402-9980, Mark.Antonino@fda.hhs.gov.

Sincerely,

Mark J. Antonino -S

Mark J. Antonino, M.S.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

NOV 15 1993

D. Eugene Hokanson
President
D.E. Hokanson, Inc.
12840 Northeast 21st Place
Bellevue, Washington 98005

Re: K932851/S2
Disposable Penile Blood Pressure Cuffs
Dated: September 7, 1993
Received: September 9, 1993
21 CFR 870.1120
Regulatory class: II

Dear Mr. Hokanson:

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 to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). General controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practices, 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. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal laws or regulations.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence for your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device, please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-326), at (301) 594-4639. 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 at (301) 443-6597.

Sincerely yours,

Lillian Yin

Lillian Yin, Ph.D.
Director, Division of Reproductive, Abdominal, Ear, Nose and Throat, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

K932851/5

Hokanson

D. E. Hokanson Incorporated
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Bellevue Washington 98005 USA

Phone 206 - 882 - 1689
FAX 206 - 881 - 1636

NOV 15 1993

July 16, 1993

Food and Drug Administration
Mail Stop HFK-450
8757 Georgia Avenue
Silver Springs, MD 20910

Supplement to 510(k) Number: K932851
Product: Disposable Penile Blood Pressure Cuffs.

Subject: Safety and Effectiveness

Safety. The disposable penile blood pressure cuffs are constructed of vinyl backed Velcro loop and virgin polyvinyl chloride plastic. These are materials people handle frequently with no known problems. The cuff comes in contact with the patient's skin. At this point the cuffs are not sterilized, although they could be. The safety comes from the disposable nature of the cuffs which are intended for single-patient use.

Effectiveness. The cuffs are the same size as the non-disposable penile cuffs which we have sold for many years. The ability of a blood pressure cuff to correctly measure pressure depends on its size and ability to compress the member being measured. All of our penile cuffs (disposable and non-disposable) have a non stretchy backing and a soft inner side facing the penis. When the cuffs are inflated the thin inner wall of the cuff easily moves inward and transmits essentially all the pressure to the penis. This insures accuracy. All blood pressure cuffs work this way and I believe the technique is well enough accepted so as no to require additional proof.

Sincerely,

D. Eugene Hokanson

D. Eugene Hokanson
President

DEH:laf