D.E Hokanson, Inc.
c/o Mr. D. Eugene Hokanson
President
12840 N E 21st Place
Bellevue, WA 98005

Re: K041689
Trade Name: Hokanson Blood Pressure Digit and Penile Cuffs
Regulation Number: 21 CFR 870.1120
Regulation Name: Blood Pressure Cuff
Regulatory Class: II (two)
Product Code: DXQ
Dated: July 14, 2004
Received: July 19, 2004

Dear Mr. Hokanson:

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) 594-4648. 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 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,

[Signature]

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

Enclosure
Indications for Use

510(k) Number (if known): K041689

Device Name: Hokanson Blood Pressure Digit and Penile cuffs

Indications For Use:

Hokanson Digit and Penile cuffs are intended to measure blood pressure in small peripheral body parts or small infants. For accuracy, the width of a blood pressure cuff should be approximately the same as the diameter of the limb or digit being measured. The length of the cuff, in the case of these devices, is long enough to completely encircle the object being measured. The usage is the same as the predicate device which has been manufactured by our company since 1973.

Prescription Use  AND/OR  Over-The-Counter Use X
(Part 21 CFR 801 Subpart D)  (21 CFR 801 Subpart C)

(Please do not write below this line-continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Number K041689