K032821

DEC - 5 2003

E. 510(k) Summary of Safety and Effectiveness

Submitter: Hygia Health Services, Inc.
434 Industrial Lane
Birmingham, Alabama 35211

Date: June 21, 2003

1. Contact Person

Ms. Tracy Comas
Chief Operating Officer
Tel: 205-314-3920
Fax: 205-314-3959

2. Name of Device

Classification Name:	Cuff, Blood Pressure CFR 870.1120
Common or Usual Name:	Blood Pressure Cuff
Review Panel:	Cardiovascular
Classification:	Class II
Product Code	DXQ
Proprietary Name:	Hygia Health Services Reprocessed Blood Pressure Cuff.

3. Predicate Devices

Device	Manufacturer	510(k)
Critikon Soft Blood Pressure Cuff	Johnson and Johnson	K974080
Disposa-Cuff® blood pressure cuff	Crest Medical Equipment	K790810
Surgi-Cuff®	Ethox Corporation	K883977
CUFF-ABLE® Cuff	Vital Signs, Inc. (Bio-Medical Dynamics)	K911213
Statcorp Disposable Blood Pressure Cuff	Statcorp, Incorporated	K940214
Technicuff®	TECHNICUFF CORP.	K942259
Cloud Cuff®	Parts Port, Ltd	K002360

4. Device Description

Per CFR 870.1120, a Blood Pressure Cuff is a device that has an inflatable bladder within, or integral to, an inelastic sleeve (cuff) with a mechanism for inflating and deflating the bladder. The cuff is used in conjunction with an appropriate measuring device to determine a subject's blood pressure.

The Hygia Health Services Reprocessed Blood Pressure Cuff comprises tubing attached to a soft inelastic sleeve with an integrated inflatable bladder that is wrapped around the patient's limb and secured by hook and loop closure. The device tubing is connected to an appropriate non-invasive blood pressure measurement system. The blood pressure cuffs contain no latex. Sizes include neonatal through large adult. Each cuff is packed in a sealed polyethylene (non-sterile) bag and each cuff is marked with the effective size range of limbs on which it may be used.

5. Intended Use

The Hygia Health Services Reprocessed Blood Pressure Cuff is intended to be used in conjunction with non-invasive blood pressure monitoring systems by personnel properly trained in the use of manual or automatic sphygmomanometers as appropriate. The device is non-sterile and is intended as a single patient use device. It is available in neonatal through large adult size.

6. Technological Characteristics

The technological characteristics of the Hygia Health Services Reprocessed Blood Pressure Cuff are identical to the originally manufactured Blood Pressure Cuff in design, materials, energy source, mode of operation, and performance characteristics. Some of the original devices are indicated for multiple patient usage whereas the Hygia Health Services reprocessed devices are indicated for single patient use only. The only differences between the original devices and the reprocessed devices are with respect to changes that result from the cleaning, disinfection, repackaging and relabeling processes used by Hygia Health Services to prepare the used original devices for safe and effective use on other patients as a single usage device.

7. Performance Data

Non-clinical Tests- Comparative bench testing was utilized to assess and prove similarity of function between the Hygia Health Services Reprocessed Blood Pressure Cuff and the predicate devices. Tests showed that the functional and operational performance characteristics including compression, pressure control, leakage, and both safety and operational parameters used when connected to inflation and measurement equipment were substantially equivalent.

Test Conclusions- Non-clinical test results of the Hygia Health Services Reprocessed Blood Pressure Cuff indicated substantial equivalence in the measured characteristics to the predicate devices, the as originally manufactured blood pressure cuffs.

8. Statement of Substantial Equivalence

The Hygia Health Services Reprocessed Blood Pressure Cuff is substantially equivalent in technology, function, operating parameters, and intended use to Blood Pressure Cuffs that are currently commercially available and in distribution. The original devices may be marked for "single-patient use only" or for "multiple uses". After reprocessing, they are marked for "single patient use" only. Hygia Health Services does not change the device in any way except to return the device to a "usable" condition by processing it through a scientifically validated disinfection procedure. The Hygia Health Services high level disinfection (HLD) protocol does not alter the efficacy, safety, composition, or intended use of the device. The basis of operation for the devices is the inflation of a bladder, which is placed around the patient's limb. The cuff is connected to a compatible inflation device. Inflation of the device may be accomplished either manually or automatically according to the type of instrument used.

9. Hygia Reprocessed BP Cuffs

Manufacturer	Product
Allegiance Healthcare	Tactics Soft Blood Pressure Cuff
Welch Allyn	Soft Blood Pressure Cuff
Johnson & Johnson	Critikon Soft Cuff
Kimberly-Clark Corporation	Soft and Vinyl Personal Cuff
Spacelab Medical	Tru-cuff vinyl and soft
Kimberly Clark Corporation	Novaplus soft disposables
Vital Signs	Cuffable
Technicuff	BP Cuff
Medline	BP Cuff Soft and Vinyl

Note: Welch Allyn manufacturers and private labels BP cuffs for Allegiance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 5 2003

Hygia Health Services
c/o Mr. Tracy Wood Comas
Chief Operating Officer
434 Industrial Lane
Birmingham, Alabama 35211

Re: K032821
Trade Name: Reprocessed Blood Pressure Cuffs
Regulation Number: 21 CFR 870.1120
Regulation Name: Blood Pressure Cuff
Regulatory Class: Class II (two)
Product Code: NPP
Dated: November 24, 2003
Received: November 25, 2003

Dear Mr. Comas:

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. 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,

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

Enclosure

Hygia Health Services 434 Industrial Lane Birmingham, AL 35211
1-866-943-6670

Contents: Reprocessed and Repacked Medical Device
Original Equipment Manufacturer (OEM): Critikon

OEM Catalog #: **2363** Hygia Catalog #: **HHS-2363**

Product Description: **Soft-Cuf™ Adult Cuff Size 23-33cm**

For Single Patient Use Only Non-Sterile, Latex Free
Caution: Federal Law restricts this device to sale by or on order of a physician.

Instructions for Use:

1. Place cuff under upper arm of patient.
2. Fold side of cuff with dashed index line over patient's arm.
3. Fold Velcro® side of cuff over dashed index side. Secure Velcro® attachment.
4. Insure that the tube is directed down away from the cuff.
5. Insure that the cuff is securely attached to the patient.
6. Inflate cuff.

Indications:

The Hygia Health Services Reprocessed Blood Pressure Cuff is an accessory used by trained personnel in conjunction with non-invasive blood pressure measurement systems, primarily in a clinical setting.

Cautions:

1. Proper cuff application is essential.
2. Cuff should be removed immediately if the patient experiences tingling, numbness, or pain. The physician should be notified.
3. Cuff should not be used over an open wound, gangrene, untreated infected wound, recent skin grafts, or dermatitis.
4. Cuff should not be inflated too tightly so as not to occlude circulation.
5. If inflated too loosely, the cuff will not deliver maximum benefits.

Contraindications:

The Hygia Reprocessed Blood Pressure Cuff should NOT be used in the following conditions:

1. Any local condition in which the garment would interfere:
   - open wounds
   - untreated infected wounds
   - gangrene
   - recent skin graft
   - dermatitis

(Sign-Off)
Cardiovascular Devices

Number K032821

Prescription Use ___ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)