

K974080

MAY 18 1998

510(k) Summary

Date October 27, 1997

Contact Darlene T. Korab
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Regulatory Affairs
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Device Name • CRITIKON* Soft Blood Pressure Cuff

The subject of this premarket notification is a modification of the currently marketed Johnson & Johnson Medical, Inc. CRITIKON Soft Blood Pressure Cuff (formerly DISPOSA-CUF* Soft Blood Pressure Cuff).

Common Name • Blood Pressure Cuff

Classification The classification name, 21 Code of Federal Regulations (CFR) Part and Paragraph number, product code and classification of the CRITIKON Soft Blood Pressure Cuff follow. The tier categorization based on the list (January 27, 1994) distributed by the Office of Device Evaluation is also included.

Classification Name	21 CFR Section	Product Code	Class	Tier
Blood Pressure Cuff	870.1120	DXQ	II	2

Continued on next page

510(k) Summary, Continued

Predicate Devices

The CRITIKON Soft Blood Pressure Cuff is substantially equivalent to the CRITIKON (formerly DISPOSA-CUF) Soft Blood Pressure Cuff currently marketed by Johnson & Johnson Medical, Inc. The original DISPOSA-CUF Blood Pressure Cuff received market clearance on May 25, 1979 via Crest Medical Equipment 510(k) K790810. The device is virtually the same as the CRITIKON or DISPOSA-CUF Soft Blood Pressure Cuff. The CRITIKON Soft Blood Pressure Cuff is also substantially equivalent to the CUFF-ABLE* Blood Pressure Cuff currently marketed by Vital Signs, Inc. [Biomedical Dynamics 510(k) K911213] and other soft blood pressure cuffs.

Device	Manufacturer	510(k)
CRITIKON (formerly DISPOSA-CUF) Soft Blood Pressure Cuff	Johnson & Johnson Medical, Inc.	K790810
SURGI-CUF* Cuff	Ethox Corp.	K883977
CUFF-ABLE Cuff	Vital Signs, Inc.	K911213
Cuff-m* Cuff	Lorin Medical	K921997
Soft Check* Cuff	Statcorp, Inc.	K940214
Safe-Cuff* Cuff	CAS Medical Systems	Unknown

Device Description

The device 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 a non-invasive blood pressure measurement system.

The device is available in the following configurations:

- five neonatal and eight pediatric and adult sizes
- single and dual cuff tubing, connectors, adapters and bulb/valve assemblies available for use with a variety of manual and automated sphygmomanometers

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510(k) Summary, Continued

Indications The CRITIKON Soft Blood Pressure Cuff is an accessory used in conjunction with non-invasive blood pressure measurement systems. The device is non-sterile and semi-disposable (may be single-patient use or optional limited reuse). It is available in neonatal, pediatric and adult sizes. The device is not designed, sold, or intended for use except as indicated.

Technological Characteristics The CRITIKON Soft Blood Pressure Cuff is virtually the same as the CRITIKON or DISPOSA-CUF Soft Blood Pressure Cuff with the exception of a modification of the sleeve material to afford greater patient comfort. The CRITIKON Soft Blood Pressure Cuff is also virtually the same as the CUFF-ABLE Blood Pressure Cuff and other soft blood pressure cuffs. All the above devices are available in range of neonatal, pediatric and adult sizes and configurations for use with a wide variety of manual and automated sphygmomanometers.

Performance Bench and laboratory testing was conducted to demonstrate performance (safety and effectiveness) of the CRITIKON Soft Blood Pressure Cuff:

- Biocompatibility
- Validation of reprocessing
- Repeated inflations

Conclusions In accordance with the Federal Food, Drug and Cosmetic Act and 21 CFR Part 807, and based on the information provided in this premarket notification, Johnson & Johnson Medical concludes that the modified device, the CRITIKON Soft Blood Pressure Cuff, is safe, effective and substantially equivalent to the predicate devices as described herein.

Other Information Johnson & Johnson Medical, Inc. will update and include in this summary any other information deemed reasonably necessary by the FDA.

Johnson & Johnson
MEDICAL INC.

October 6, 1997

Critikon, a division of Johnson & Johnson Medical, Inc., certifies that the instructions for reprocessing for CRITIKON™ Soft Blood Pressure Cuffs as available in the Instructions for Use (P/N 714338) have been validated according to a formal protocol (052496), comprising sound scientific principles and laboratory procedure. The protocol is conceptually based on AAMI TIR No. 12-1994, "Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Device Manufacturers." A summary of the validation procedure is attached. The protocol and subsequent laboratory report are archived in Critikon Technical File 103-1 under change control. They will be made available for inspection or supplied to FDA upon request.



John P. Clemmons
Critikon R&D



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 18 1998

Ms. Darlene T. Korab
Johnson & Johnson Medical, Inc.
4110 George Road
Tampa, FL 33634

Re: K974080
CRITIKON® Soft Blood Pressure Cuff
Regulatory Class: II (two)
Product Code: 74 DXQ
Dated: February 13, 1998
Received: February 17, 1998

Dear Ms. Korab :

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.

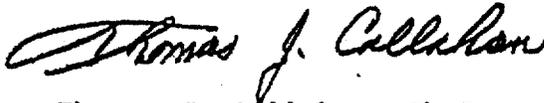
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, 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.

Page 2 - Ms. Darlene T. Korab

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) 594-4648. 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,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

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510(k) Number (if known): K97 4080

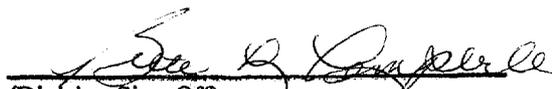
Device Name: CRITIKON* Soft Blood Pressure Cuff

Indications for Use:

The CRITIKON Soft Blood Pressure Cuff is an accessory used in conjunction with non-invasive blood pressure measurement systems. The device is non-sterile and semi-disposable (may be single-patient use or optional limited reuse). It is available in neonatal, pediatric and adult sizes. The device is not designed, sold, or intended for use except as indicated.

(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 Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K97 4080

Prescription Use
(per 21 CFR 801.109)

OR

Over-The Counter Use
(Optional Format 1-2-96)