

K963987

10-1

510K Summary

JUL 23 1997

Submitter N.A. Braggs Medical, Inc.
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Contact Person- Jacqueline Brackett
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Date of Preparation- September 25, 1996
Date of Revision #1- January 8, 1997
Date of Revision #2- April 12, 1997

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Device Name- Camouflage Cuff Saver

Common Name- Cuff Protector/Bladder Cover

Registration Number- 1060936

Classification- Cardiovascular. No classification listed. Device not listed in 21 CFR Parts 862-892.

10-3

Legally Marketed Device to Which Equivalence is Claimed:

We claim equivalence to 21 CFR section 870.1120- Blood Pressure Cuff. Predicate devices to which equivalence is claimed listed below.

1. Vital Signs Clean Cuff- K912638
2. Criticon Disposables (no number on record according to the Southeast Region Small Business Office of the FDA).
3. Bowen Medical Services Cuff Guard- K952825

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Identification of the Equivalent Device:

We compare the Cuff Saver, which is essentially a paper drape, to two (2) known disposable blood pressure cuffs (Vital Signs Clean Cuff K912638 and Criticon Disposables [no K number]. Both of these are vinyl/latex composition and are labeled in print by the manufacturer for single patient use. We also compare our device to Bowen Medical Cuff Guard K952825. Our device is less costly than our competitors (< \$1.00 vs. > \$5.00). As we understand the classification system, these vinyl/latex cuffs and cuff covers considered Class 2. We also have identified Patent Number 5,228,448 for a protective cover for blood pressure cuffs. The above identified cover is designed to be placed about the patient's arm and the blood pressure cuff is then placed atop the cover. The cover is folded over the cuff at that time. It is constructed of a two-ply fabric with one layer being absorbent and the other fluid repellent. The construction and application of this device make it complicated to manufacturer and time consuming to use. At this time, we do not know of

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anyone offering this device for sale in the medical industry. Our product is manufactured of fluid repellent medical grade Sontara non woven fabric. Camouflage Cuff Savers may also be used as the cuff itself when paired with the commercially available cuff inflation bag/bladder and, as such, serves to function as the disposable member of the blood pressure cuff in addition to it's role as a protective cover for reusable cuffs. The non woven fabric is a strong, fluid repellent substrate and the double sided adhesive tape used forms a strong secure bond when applied to the material. This allows the Cuff Saver to cover a cuff Bladder and thus become a reliable blood pressure cuff for single patient use.

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Description of the Device:

The Camouflage Cuff Saver is essentially a non woven paper drape that can cover/contain a normal blood pressure cuff, a disposable cuff, or a cuff bladder. It is fluid repellent and acts to ensure a clean cuff for each patient as it is discarded after single patient use. It is manufactured of medical grade Sontara non woven fiber with 3M brand double sided adhesive tape as a fastening along one vertical edge of the unit and an adhesive patch located on the printed side of the unit. This patch is used to secure the device to its own surface after the device and the cuff it covers are applied to the patients arm. As stated, the device is printed with a design and typical marking for a blood pressure cuff (Artery placement, Range line, etc.). It is available on a perforated roll so that the user can tear off one unit at a time just as one removes a paper towel from its roll.

It has been the concern of many health care workers that the blood pressure cuff is a potential source of contamination in the hospital environment. Reusable cuffs are difficult, if not impossible to clean and, more often than not, are never cleaned. "Single use Only" cuffs are used until they deteriorate and are also poorly cleaned. Blood pressure cuffs used in the surgical suite remain on the patient when the patient is transported to the ICU or recovery room. This represents a poor understanding of infection control standards. The Cuff Saver attempts to address these problems by providing a clean, cost effective alternative to the current market.

Cuff Savers do not interfere with the performance of the functional cuff that it serves to cover and may also be used as the cuff itself when used to cover a cuff bladder. The Cuff Saver is soft, clean, covers the blood pressure cuff, and after use, is discarded. This prevents contaminated cuffs from being transmitted with their contaminants to the recovery or critical care areas of the hospital.

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Intended Use of the Device:

The general intended use of the Cuff Saver will be to cover all blood pressure cuffs prior to being applied to the patient. As stated earlier, it can also cover a cuff bladder and be used as the cuff itself. When used as a cover or disposable blood pressure cuff, this will keep the patient from being exposed to a dirty cuff and will also protect the health care worker from overt and covert exposure. The device will also serve to protect the reusable cuff from soiling and thus prolong the life of the reusable cuff.

The entire general patient population will be impacted with the use of the Cuff Saver. Health care workers will be impacted as well. Dirty blood pressure cuffs should no longer be a problem as, once cleaned, the Cuff Saver will protect blood pressure cuffs and cuff bladders from further contamination. By using the Cuff Saver in combination with the inflation bladder as the cuff, cleanliness can be assured because the Cuff Saver can be discarded and the bladder can be easily cleaned due to its non porous surface. The older unsanitary reusable cuffs that employ Velcro as their fastenings are impossible to clean and retain all sorts of surface material and contaminants. Cuff Savers do not use Velcro as a fastening. Instead, a very strong double sided adhesive tape is used to attach the cuff surfaces to each other. No adhesive is in contact with the patients skin.

Since it has been shown in the current medical literature that standard blood pressure cuffs harbor pathogens, it follows that the Camouflage Cuff Saver should and will be of great benefit in protecting the patient and the health care worker from pathogens. It should also be of use in the prevention of transference of disease and nosocomial infection. In light of these potential health benefits to the general public, we request that Camouflage Cuff Savers be considered for Expedited Review.

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Determination of Substantial Equivalence and Testing Summary:

Basically, the Camouflage Cuff Saver is a disposable blood pressure cuff designed to be used in conjunction with a reusable cuff or commercially available inflation bag/bladder. When applied to the reusable cuff, it does not alter the performance of said cuff, yet it protects the cuff from contamination and soiling. When used with the inflation bladder, it functions as a disposable cuff itself and performs as well as a standard cuff. Clinical tests performed by N. A. Braggs Medical, Inc. on seventeen human volunteers of various sizes and upper arm circumference provide credible proof. Tests were performed with standard sizes of commercially available blood pressure cuffs of both the reusable and disposable varieties. Cuffs of the bladder type and the bladderless

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type were tested with and without the application of the Camouflage Cuff Saver device. The Cuff Saver was also tested with the standard commercially available inflation bladder with the Cuff Saver covering the bladder and the Cuff Saver acting as the Cuff itself. Each subjects pressure was taken in the order listed with a three minute waiting period between each measurement. The pressures were taken using a Dinamap Brand noninvasive blood pressure machine. Measurement accuracy was confirmed by checking the Dinamap machine against pressure taken with a calibrated mercury sphygmomanometer. For accuracy, cuffs used on each volunteer were at least 40% as wide as the circumference of the subjects upper arm. All subjects were awake and in an unaltered state of awareness during the testing.

The finding of the testing process showed no discernible or appreciable difference between the blood pressures taken with the conventional blood pressure cuffs and those fitted with the Camouflage Cuff Saver device. There was also no appreciable or discernible difference between the blood pressures taken with the conventional cuff and those taken with the Camouflage Cuff Saver fitted with the standard inflation bladder. All of the measurements obtained conformed to the data acceptance limits set forth in the testing protocol and all results conformed to the pass/fail criteria of a 95% Confidence interval of 4.3 or less derived from data collected from measurement of blood pressure taken with the calibrated Dinamap brand blood pressure machine and the two industry standard cuffs used in the study. Minor fluctuations in the results obtained are attributed to the dynamic state of blood flow within the cardiovascular system and are physiologic in nature. In conclusion, Camouflage Cuff Savers offer the public a functional, inexpensive alternative to the current disposables on the market today and provide a public health benefit to the general population by reducing the incidence of cross-contamination.

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Safety and Effectiveness- Information contained in the body of the notification accompanying this summary provides biocompatibility data for the materials used in the construction of this device. Materials consist of DuPont Sontara F802 nonwoven fiber (55% polyester, 45% wood pulp), and 3M brand No. 9890 Double Coated Medical tape on a liner. Both products are biocompatible according to the test information supplied by the respective companies. Both products are already in use in the medical industry. Ink information is also supplied in the body of the notification and complies with national industry safety standards. Effectiveness of the device is confirmed by statistical analysis of data contained in the Investigational Study located in the body of this 510(k) notification. Study data indicated that the Camouflage Cuff Saver can function safely as a blood pressure cuff or as a cuff cover. Slight variations in the readings are physiologic and represent the dynamic state of the cardiovascular system. In a study conducted by Martin G. Myers, M.D. , protecting cuffs during patient contact resulted in a marked and rapid decrease in the infection rate.(1) Reinforcing this literature is the small culture study performed in a working operating room by this company. In our study, the cuff that was protected with our device during patient contact produced "no growth 48 hrs" and a 0 colony count. This was not the case with the unprotected cuffs which all grew bacteria. The world wide web was thoroughly searched for information pertaining to national or international standards for blood pressure cuffs. Apparently none exist. The F.D.A. has no performance standards for blood pressure cuffs. The American Heart Association was contacted for information pertaining to cuff standards. There were no direct standards. Their recommendations for accuracy include monthly calibration of manual home sphygmomanometer units against an aneroid or mercury sphygmomanometer and use of the correct size cuff to limb ratio (the cuff should be at least 40% as wide as the circumference of the limb to which it is applied). The Camouflage Cuff Saver complies with these AHA recommendations.

(1)"Longitudinal Evaluation of Neonatal Nosocomial Infections: Association of Infection with Blood Pressure Cuff," Martin G. Myers, M.D., Pediatrics, January 1978, 61, No. 1. p. 42-45.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

Ms. Jacqueline Brackett
CEO
N.A. Braggs Medical, Inc.
8255 Brackett Lane
Semmes, Alabama 36575

JUL 23 1997

Re: K963987
Camouflage Cuff Savers
Regulatory Class: II (Two)
Product Code: 74 (DXQ)
Dated: April 25, 1997
Received: May 1, 1997

Dear Ms. Brackett:

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 (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. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, 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.

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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

510(k) Number (if known): K 963987

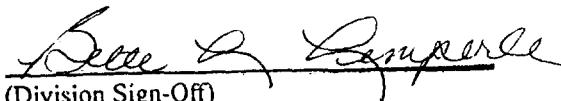
Device Name: Camouflage Cuff Saver

Indications For Use:

The intended use of the Cuff Saver will be to cover all types of blood pressure cuffs and/or cuff bladders prior to the cuff or cuff bladder being applied to the patient. This will protect the patient and the health care worker from overt and covert exposure to soiled or contaminated blood pressure cuffs.

(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 K 963987

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____