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510 (K) SUMMARY
(ANNEXURE 5)

Date prepared
May 24, 2004
Muhamad Ansari
Busse Hospital Disposables
PO Box: 11067
75 Arkay Dr.
Hauppauge NY 11788

Device Common, Usual, or Classification Names: Urethral Catheter.

Classification Panel: Classification of this device would fall under the responsibility of the Gastroenterology – Urology device panel.

Classification: Class II, 21 CFR 876.5130, GBM

Description of the Device:

5FR 9", 8FR 9" and 8FR 6" Catheters: clear virgin PVC.
The catheter consist of a PVC tube with 2 or 3 drainage eyes on the proximal tip. The catheter is available in a combination of French sizes and lengths to accommodate pediatric and adult male and female applications.

The Catheter is used in urinary collection procedure, this procedure is a way of obtaining a urine sample through a catheter (a thin PVC tube) inserted through the urethra into the bladder. The urine is obtained by this method to avoid contamination from the urethra, or if urine cannot be collected by the clean catch method.

The Urethral Catheter is packaged as part of a convenience kit for Urine Catheter Kit. The Urethral Catheter packaged in a soft pouch with Tyvek lid. The pouch is heat-sealed.

The convenience kit includes a variety of devices used in the Urinary Catheter procedure including vial, gloves, iodophor PVP Swabsticks, embossed drape, and lubricating jelly. The other convenience kit are either exempt from 510(k) or are purchased from other manufacturers who have obtained 510(k) clearance on the devices. Busse certifies that the devices in the kit are either legally marketed preamendment devices, are exempt from premarket notification, or have been found to be substantially equivalent through the premarket notification process for the use for which the kit is to be intended.

The subject devices are composed of the following materials:

Component	Material	Details
Catheter	Clear Virgin PVC	Inserted into the urinary tract

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Intended Use [21 CFR 807.92(a)(5)]
This device is a tubular device that is inserted through the urethra and utilized for passage of fluids from or to the urinary tract.

Technological Characteristics [21 CFR 807.92(a)(6)]
Busse Hospital Disposables, Inc. believes that the subject device is substantially equivalent to the predicate device.

Busse Hospital Disposables, Inc. believes that the subject device is substantially equivalent to other devices that have previously received FDA 510(k) clearance including the predicate device.

Conclusion [21 CFR 807.92(b)(3)]

We believe the differences between the subject device and predicate device are minor and conclude that the subject devices are as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 5 2004

Mr. Muhamad Ansari
Quality Manager
Busse Hospital Disposables
P.O. Box 011067
HAUPPAUGE NY 11788

Re: K041464
Trade/Device Name: Busse Hospital Disposable Urethral Catheter
Regulation Number: 21 CFR §876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: 78 EZD
Dated: October 20, 2004
Received: October 20, 2004

Dear Mr. Ansari:

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 (the Act). You may, therefore, market the device, subject to the general controls provisions of Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note:* If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. 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 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.

In addition, we have determined that your device kit contains Iodophor PVP Swabsticks and Lubricant Jelly which are subject to regulation as drugs.

Our substantially equivalent determination does not apply to the drug components of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with the drug components. For information on applicable Agency requirements for marketing these drugs, we suggest you contact:

Director, Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 594-0101

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, please contact the Office of Compliance at (301) 594-4616. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 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/dsma/dsmamain.html

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K041464

Device Name: Busse Hospital Disposable Urethral Catheter.

The device is a tubular device that is inserted through the urethra and utilized for passage of fluids from or to the urinary tract.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041464