DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 26 2004

Mr. Michael Czop
Contour Fabricators, Incorporated
4100 E. Baldwin Road
Grand Blanc, Michigan 48439

Re: K970185
Trade/Device Name: Sterile Disposable Equipment Magnet Cover
Regulation Number: 21 CFR 878.4370
Regulation Name: Surgical Drape and Drape Accessories
Regulatory Class: II
Product Code: KKX
Dated: March 27, 1997
Received: March 28, 1997

Dear Mr. Czop:

This letter corrects our substantially equivalent letter of April 10, 1997 regarding the product code.

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 (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.

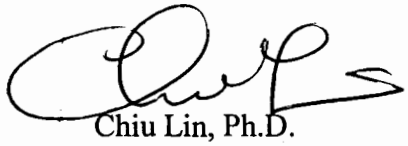
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 continue 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 (240) 276-0115. 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,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(K) SUMMARY
(as required by 807.92(c))

K970185
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Submitter of 510(k):

Contour Fabricators, Inc.
4100 East Baldwin Rd.
Grand Blanc, MI 48439

Phone: (810)695-2910
Fax: (810)695-5336

APR 10 1997

Contact Person: Michael W. Czop

Date of Summary: April 3, 1997

Trade Name: Sterile, Disposable Magnet Cover

Classification Name: Sterile, Disposable Equipment Cover

Predicate Device: Contour Fabricators, Inc. Bandbag, Wrap, Sterile, Disposable Flouroscope and General Equipment Cover. K782155

Bemiss-Jason Corporation (originally Triad Medical Division), E-Z Fit Cover. K831287

Device Description: The sterile, disposable magnet cover utilizes a Dexter Nonwoven: a soft, strong absorbent pinhole resistant base fabric, which has been coated with .5 mil of linear low density polyethylene extrusion. The material is blue in color, cut to an overall length and width of 114" x 54", and is 5 mils thick.

Through the use of pressure sensitive adhesive tape, the cover can be attached to a clean, dry surface to establish a barrier.

Performance Standards: Flammability:

Material was tested for flammability in accordance with 16 CFR 1610. Because the material is disposable in nature and would not withstand the rigors of washing and dry cleaning specified by the standard, the material was tested in its "as received condition." The average rate of burn for the material was 7.3 seconds, compliant with Class I flammability standards.

Grammage (Basis Weight): g/m^2		69.4
Tensile Strength, Dry: g/25mm	MD	3500
	CD	2100
Absorbency (Water Drop): sec		2.5

510(K) SUMMARY
(as required by 807.92(c))

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Performance Standards: (Continued)

Resistance to fluid penetration:

An engineering test was prepared to determine the ability of the material to resist fluid penetration. Material was subjected to fluid-depth-related pressure of .22 psi for 6 hours, visual and tactile inspection revealed no fluid penetration through the material.

Intended Use:

Magnetic Resonance Imaging (MRI) technology requires the use of large magnets for image generation. This technology is now being tested for use in surgical procedures. The sterile, disposable magnet cover is intended to protect the walls of a magnet from gross contamination and also to isolate the sterile field from microbial contamination.

This particular cover is specifically intended for use with the General Electric Medical Systems Signa SP MRI system.