K982818

OCT 21 1998

510K(k) SUMMARY

SUBMITTER: Gambro Healthcare
1185 Oak Street
Lakewood, CO 80215
(303) 231-4436

DATE PREPARED: August 5th, 1998

DEVICE NAME: Hospal TIPSTOP

CLASSIFICATION NAMES: Compression Dressing Containing Alginate

PREDICATE DEVICE: Hospal TIPSTOP

Device Description:

Hospal TIPSTOP

The Hospal TIPSTOP is a compressive dressing made of polyamide compressive element covered with alginate, which is placed on an adhesive film. TIPSTOP has been specially designed to stop bleeding after venipuncture in a manner similar to other compression dressings. The action mechanism consists of prolonging the manual compression with a mechanical compression carried out by the compressive element. TIPSTOP is sterilized by gamma irradiation. TIPSTOP is intended to be used as a sterile compression dressing for puncture of the vascular access site.

Predicate Devices:

The Hospal TIPSTOP presented in this 510(k) Notification is identical in indications for use, labeling and materials to the previously cleared Hospal TIPSTOP which was cleared by the FDA on September 10th, 1990 (K896068) with one exception. The material on the compression body has been changed from lyophilized bovine collagen to lyophilized alginate.

Intended Use:

TIPSTOP is intended to be used as a sterile compression dressing for puncture of the vascular access site.

This indication statement is essentially the same as the indication statement for the predicate device.

Technological Characteristics:

Comparing the proposed device to the predicate device, the only difference between the two devices is that the proposed device utilizes lyophilized alginate molded on to the polyamide compressive element whereas the predicate device uses lyophilized bovine collagen. This is the only significant difference.

Summary of Non-Clinical Tests:

In vitro testing was performed on the Hospal TIPSTOP to determine the biocompatibility characteristics of the lyophilized alginate. The results of these tests confirmed that the proposed device is substantially equivalent to the proposed device for these parameters.

Clinical Test Results:

Clinical testing was not performed

Conclusions:

Testing performed on the Hospal TIPSTOP indicates that they are safe, effective, and perform as well as the predicate device, when used in accordance with the instructions for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 21 1998

Jeffrey R. Shideman, Ph.D.
Gambro HealthCare
1185 Oak Street
Lakewood, Colorado 80215-4498

Re: K982818
Trade Name: HOSPAL TIPSTOP
Regulatory Class: Unclassified
Product Code: KMF
Dated: August 05, 1998
Received: August 11, 1998

Dear Dr. Shideman:

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 (the Act). You may, therefore, market your device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) and the following limitations:

1. This device may not be labeled for use on third degree burns.

2. This device may not be labeled as having any accelerating effect on the rate of wound healing or epithelization.

3. This device may not be labeled as a long-term, permanent, or no-change dressing, or as an artificial (synthetic) skin.

4. This device may not be labeled as a treatment or a cure for any type of wound.

The labeling claims listed above would be considered a major modification in the intended use of the device and would require a premarket notification submission (21 CFR 807.81).

The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, 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 (CFR), Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practices (GMP) for Medical Devices: General GMP regulation (21 CFR Part 820) and that, through periodic GMP 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.

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) 594-4595. 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,

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K982818 K982818

DEVICE NAME: Hospal TIPSTOP

INDICATIONS FOR USE:

TIPSTOP is intended to be used as a sterile compression dressing for puncture of the vascular access site.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE 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) (Optional Format 1-2-96)

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