



Allegiance Healthcare Corporation  
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K 973703

DEC - 4 1997

### **XIII. SUMMARY OF SAFETY AND EFFECTIVENESS**

#### **510(k) SUMMARY OF SAFETY AND EFFECTIVENESS**

**Jackson-Pratt® Hemaduct™**

**Jackson-Pratt Gold™ Hemaduct™ Wound Drains**

**Manufacturer:** Allegiance Healthcare Corporation  
MediVac  
1500 Waukegan Road  
McGaw Park, Illinois 60085

**Regulatory Affairs Contact:** Joseph A. Mertis  
Allegiance Healthcare Corporation  
1500 Waukegan Road  
McGaw Park, IL 60085

**Telephone:** (847) 785-3310

**Date Summary Prepared:** September 11, 1997

**Product Trade Name:** Jackson-Pratt® Hemaduct™ Wound Drain  
Jackson-Pratt Gold™ Hemaduct™ Wound Drains

**Common Name:** Surgical Wound Drain

**Classification:** Catheter, Irrigation (79GBX)

**Predicate Devices:** Jackson-Pratt® Wound Drains  
Johnson & Johnson Blake™ Drain  
Zimmer Quad-Lumen™ Drain

**Description:** The Jackson-Pratt® Hemaduct and the Jackson-Pratt Gold™ Hemaduct™ Wound Drains are made of silicone in a variety of sizes and are offered sterile in both flat and round configurations,

**Intended Use:** These wound drains are flexible, multilumen tubes, intended to be used to drain fluids (exudate) from body cavities.

CFR Citation - 21CFR 878.4200

**Equivalence:**

The Jackson-Pratt® Hemaduct™ and the Jackson-Pratt Gold™ Hemaduct™ Wound Drains are substantially equivalent to Jackson-Pratt Wound Drains, the J&J Blake™ Drain and the Zimmer Quad-Lumen™ Drain in that they provide the following characteristics:

- intended use
- size, configuration, packaging
- made of silicone

**Summary of Testing:**

<u>Test</u>	<u>Result</u>
Cytotoxicity Test	Drain does not elicit any toxic reactions to acute application.
Intracutaneous Reactivity	No reactivity was observed.
Hemocompatibility	Drains are hemocompatible exhibiting no lysis.
Systemic Toxicity	Drain does not display potential for irritation.
Sensitization	Drain does not display any potential for irritation.
Pyrogen	Drain does not illicit a pyrogenic response.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DEC - 4 1997

Mr. Joseph A. Mertis  
Director, Regulatory Affairs  
Allegiance Healthcare Corporation  
1500 Waukegan Road  
McGaw Park, Illinois 60085-6787

Re: K973703  
Trade Name: Jackson-Pratt® Hemaduct™ Wound Drains and Gold™ Hemaduct™  
Wound Drains  
Regulatory Class: I  
Product Code: GBX  
Dated: September 24, 1997  
Received: September 26, 1997

Dear Mr. Mertis:

We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices are 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 devices, 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.

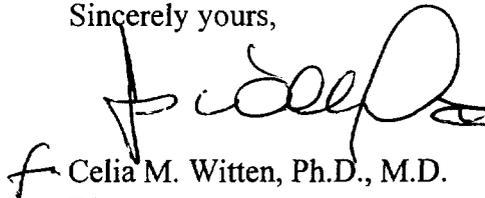
If your devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they may be subject to such additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 devices in the Federal Register. Please note: this response to your premarket notification submissions 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 devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices 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 devices, 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,

A handwritten signature in black ink, appearing to read 'Celia M. Witten', is written over a printed name. The signature is fluid and cursive.

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): K973703

Device Name: Jackson-Pratt® Hemaduct™ Wound Drain  
Jackson-Pratt Gold™ Hemaduct™ Wound Drain

Indications For Use: These wound drains are flexible, multilumen tubes, intended to be used to drain fluids (exudate) from body cavities.

CFR Citation - 21CFR 878.4200

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\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X  
(Per 21 CFR 801.109)

or

Over-The Counter Use \_\_\_\_\_

*[Handwritten Signature]*

(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number \_\_\_\_\_

K973703