K974146

JAN 28 1998

Allegiance

Allegiance Healthcare Corporation
1500 Waukegan Road
McGaw Park, Illinois 60085-6787
847.473.1500
FAX: 847.785.2461

XII. SMDA REQUIREMENTS

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
PARACENTESIS CATHETER

Manufacturer:	Allegiance Healthcare Corporation 400 East Foster Road Mannford, OK 74044
Regulatory Affairs Contact:	Sharon Robbins Allegiance Healthcare Corporation 1500 Waukegan Road MP-WM McGaw Park, IL 60085
Telephone:	(847) 785-3311
Date Summary Prepared:	October, 1997
Common Name:	Paracentesis Catheter
Classification:	Class II per 21CFR § 878.4200, Needle, Catheter
Predicate Device:	Paracentesis Catheter device, K870704 owned by Allegiance Healthcare Corporation
Description:	The paracentesis "catheter over the needle" is comprised of a Radiopaque Polyurethane Catheter over a needle with stopcock, self-sealing valve and 5 cc syringe attached.

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XII. **SMDA REQUIREMENTS (continued)**

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
PARACENTESIS CATHETER

Intended Use:	The paracentesis catheter is a device used for the therapeutic or diagnostic aspiration of fluid or air from the abdominal cavity.
Substantial Equivalence:	The proposed Allegiance Paracentesis Catheter is substantially equivalent to the currently marketed Allegiance Paracentesis Catheter in that: - intended use is the same - performance attributes are the same
Summary of testing:	All materials used in the fabrication of this paracentesis device were evaluated through biological qualification safety tests. The biocompatibility tests performed were cytotoxicity, sensitization, irritation or intracutaneous reactivity, systemic toxicity (acute) and hemocompatibility as identified on the tests for each material. These materials have met the testing requirements and were found to be acceptable for the intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 28 1998

Ms. Sharon Robbins
Manager of Regulatory Affairs
Allegiance Healthcare Corporation
1500 Waukegan Road
McGaw Park, Illinois 60085-6787

Re: K974146
Trade Name: Paracentesis Catheter Device
Regulatory Class: II
Product Code: GCB
Dated: October 30, 1997
Received: November 3, 1997

Dear Ms. Robbins:

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.

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,

for 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

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Indications for Use

510(k) Number
(if known):

Device Name: Paracentesis Catheter

Indications For Use: The paracentesis catheter is a device used for the therapeutic or diagnostic aspiration of fluid or air from the abdominal cavity.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X or Over-The Counter Use ____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K974146