

JUL 23 1998

K982269



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

**XII. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
CLEAR HUB SPINAL NEEDLE**

Manufacturer: Allegiance Healthcare Corporation
400 East Foster Road
Mannford, OK 74044

Regulatory Affairs Contact: Zarina Bilgrami
Allegiance Healthcare Corporation
1500 Waukegan Road MP-WM
McGaw Park, IL 60085

Telephone: (847) 785-3312

Date Summary Prepared: June, 1998

Common Name: Spinal Needle

Classification: Class II per 21CFR § 868.5150, Spinal, Short term
Needle

Predicate Device: Pharmaseal Clear Hub Spinal Needle
owned by Baxter Healthcare Corporation

Description: The Clear Hub Spinal Needle is a blue tinted transparent polycarbonate or acrylic hub, connected to the stainless steel cannula and hub assembly. The cannula/hub assembly provides wings and finger holds for proper control, stability and grip.

XII.

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
CLEAR HUB SPINAL NEEDLE**

Intended Use:

The Clear Hub Spinal Needle is a device used in various clinical procedures, including but not limited to, lumbar puncture, myelogram, spinal anesthesia, nerve block (pain management) and amniocentesis. The primary intended use of the Clear Hub Spinal Needle is to accommodate the procedural aspiration and /or administration of diagnostic and therapeutic fluids.

**Substantial
Equivalence:**

The proposed Allegiance Clear Hub Spinal Needle is substantially equivalent to the currently marketed Baxter Pharmaseal Clear Hub Spinal Needle in that:

- intended use is the same
- performance attributes are the same

Summary of testing:

All materials used in the fabrication of this Clear Hub Spinal Needle device were evaluated through biological qualification safety tests. The biocompatibility tests performed were cytotoxicity, sensitization, irritation/ intracutaneous reactivity and systemic toxicity (acute) 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.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 23 1998

Ms. Zarina Bilgrami
Allegiance Healthcare Corporation
1500 Waukegan Road
McGaw Park, IL 60085-6787

Re: K982269
Clear Hub Spinal Needle
Regulatory Class: II (two)
Product Code: 73 MIA
Dated: June 26, 1998
Received: June 29, 1998

Dear Ms. Bilgrami:

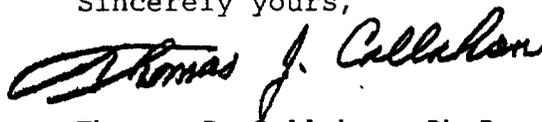
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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). 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 (Pre-market 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 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 device in the Federal Register. Please note: this response to your pre-market 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) 594-4648. 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/dsma/dsmamain.html>".

Sincerely yours,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



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847.473.1500
FAX: 847.786.2461

Indications for Use

510(k) Number (if known): Not Known

Device Name: Clear Hub Spinal Needle

Indications For Use: The Clear Hub Spinal Needle is a device which is intended for patients requiring aspiration and or injection of fluids during regional spinal anesthesia and parenteral diagnostic procedure, specifically lumbar puncture, myelogram and amniocentesis.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Mark Krause
(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices