Allegiance

Allegiance Healthcare Corporation
1500 Waukegan Road
McGaw Park, IL 60085
847.473.1500
FAX: 847.785.2461

JUN 25 1999

K991928

SUMMARY OF SAFETY AND EFFECTIVENESS

Attachment G

Manufacturer:	Allegiance Healthcare Corporation V. Mueller Business Unit 1430 Waukegan Road McGaw Park, IL 60085
Regulatory Affairs Contact	Patricia Sharpe-Gregg 1500 Waukegan Road McGaw Park, Illinois 60085
Telephone:	(847) 578-3636
Date Summary Prepared:	June 1, 1999
Product Trade Name:	Modular Endoscopy Laparoscopic Scissors, Grasping Forceps, Dissectors and Needle Holders
Common Name:	Laparoscopic Scissors, Grasping Forceps, Dissectors & Needle Holders
Classification:	Gynecologic Laparoscope and Accessories
Predicate Device: (K931340)	"Resposable" Grasping Forceps/ Scissors/ Needle Holder/ Dissectors
Description:	The Allegiance Modular Endoscopy Laparoscopic Scissors, Grasping Forceps, Dissectors and Needle Holders are composed of a reusable handle and shaft assembly and a removable tip assembly. These instruments are designed and manufactured specifically for the purpose of manipulating soft tissue structures.

Intended Use:	The Allegiance Modular Endoscopy Laparoscopic Scissors, Grasping Forceps, Dissectors and Needle Holders are used as accessories in general laparoscopic diagnostic and surgical procedures for manipulating tissue (grasping, cutting, dissecting coagulating and suturing).
Substantial Equivalence:	The Modular Endoscopy Laparoscopic Scissors, Grasping Forceps, Dissectors and Needle Holders are substantially equivalent to the Allegiance the "Resposable" Grasping Forceps/ Scissors/ Needle Holder/ Dissectors, in that: • Intended use is the same • Performance attributes are the same • Materials and basic design are the same
Summary of Testing:	All materials used in the composition of the Modular Endoscopy Laparoscopic Scissors, Grasping Forceps, Dissectors and Needle Holders were subjected to performance and physical tests to evaluate the safety, effectiveness and reliability of the device. All test results were acceptable.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 25 1999

Ms. Patricia Sharpe-Gregg
Manager, Regulatory Affairs
Allegiance Healthcare Corp.
1500 Waukegan Road
William Merz Building
McGaw Park, Illinois 60085

Re: K991928
Trade Name: Modular Endoscopy Laparoscopic Scissors, Grasping Forceps, Dissectors, and Needle Holders
Regulatory Class: II
Product Code: GCJ
Dated: June 7, 1999
Received: June 8, 1999

Dear Ms. Sharpe-Gregg:

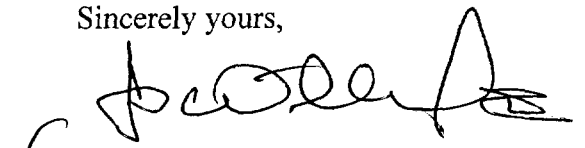
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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,



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

Allegiance

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847-578-3636 FAX: 847-785-2461

Special 510(k) Device Modification: Laparoscopic Grasping Forceps, Scissors, Needle Holders & Dissectors

V. Mueller Business Unit

510(k) Number (if known): ~~Unknown~~ K991928

Device Name: Laparoscopic Grasping Forceps, Scissors, Needle Holders and Dissectors

Indications For Use: Used as accessories in general laparoscopic diagnostic and surgical procedures for manipulating tissue (grasping, cutting, coagulating, dissecting and suturing).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K991928