DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 1 2005

Ms. Elizabeth Renken
Regulatory Affairs Specialist
Alliance Medical Corporation
10232 South 51'' Street
Phoenix, Arizona 85044

Re: K012603 Supplemental Validation Submission
Trade/Device Name: Alliance Medical Corporation Reprocessed Unipolar Laparoscopic/Endoscopic Instruments (See Enclosed List)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: NUJ
Dated: March 14,2005
Received: March 15,2005

Dear Ms. Renken:

The above-referenced premarket notification (510(k)) was cleared by the Office of Device Evaluation (ODE) on November 7,2001. We have received your supplemental validation data as required for reprocessed single-use devices by the Medical Device User Fee and Modernization Act of 2002. After reviewing your supplemental validation data, we have determined the devices listed in the enclosure accompanying this letter are 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) that do not require approval of a premarket approval application (PMA). You may, therefore, market these 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.

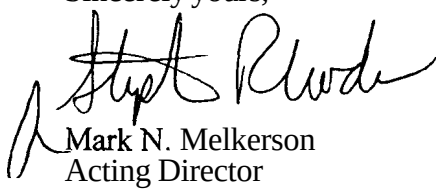
If your devices are classified (see above) into either class II (Special Controls) or class III (PMA) they may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your devices in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your devices comply with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's applicable requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

The FDA finding of substantial equivalence of your devices to legally marketed predicate devices results in classification for your devices and thus, permits you to legally market the devices. This letter will allow you to continue marketing the devices listed in the enclosure accompanying this letter.

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at 240-276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer 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,



Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K012603

Manufacturer	Description	Model
US Surgical	Autosuture ® Endo Mini-shears	174301
US Surgical	Autosuture ® Endo Shear Short	174501
US Surgical	Autosuture ® Endo Shear Long	174601
US Surgical	Autosuture ® Endo Mini-shears short	174503
US Surgical	Autosuture ® Endo Shears	176643
US Surgical	Autosuture ® Endo Dissect	176645
US Surgical	Autosuture ® Endo Dissect, Short	174505

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K012603

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II. Indications for Use Statement

510(k) Number (if known): K012603

Device Name: Alliance Medical Corporation Reprocessed Unipolar Laparoscopic/Endoscopic Instruments

Indications for Use: Reprocessed Unipolar Laparoscopic/Endoscopic Instruments, including scissors, dissectors, and graspers, are to be used for patients requiring minimally invasive surgical procedures to manipulate and manage internal soft tissue by grasping, cutting, dissecting, cauterizing, or coagulating tissue.

Manufacturer	Description	Model
US Surgical	Autosuture ® Endo Mini-shears	174301
US Surgical	Autosuture ® Endo Shear Short	174501
US Surgical	(Autosuture® Endo Shear Long	174601
US Surgical	Autosuture ® Endo Mini-shears short	174503
US Surgical	Autosuture ® Endo Shears	176643
US Surgical	Autosuture ® Endo Dissect	176645
US Surgical	Autosuture ® Endo Dissect. Short	174505

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **or** **Over-the-counter Use** ____
(per 21 CFR801.109)

Susan Walker, MD
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K012603