



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

SEP - 7 2005

Mr. David A. Alexander  
President/CTO  
Applied Surgical, LLC  
300 Riverchase Parkway East  
Birmingham, Alabama 35244

Re: K051831

Trade/Device Name: Gemini Surgical Control & Display System  
Regulation Number: 21 CFR 878.4400  
Regulation Name: Electrosurgical cutting and coagulation device and accessories  
Regulatory Class: II  
Product Code: GEI  
Dated: August 18, 2005  
Received: August 22, 2005

Dear Mr. Alexander:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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.

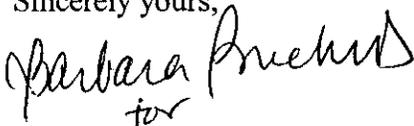
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Page 2- Mr. David A. Alexander

This letter will allow you to begin marketing your device as described in your Section 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), 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,  
  
for

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

Enclosure

**Indications For Use**

510(k) Number: K051831

Device Name: Gemini Surgical Control & Display System

**Indications For Use:**

The Gemini Surgical Control & Display System is indicated for use in any surgical procedure where single or multiple electro-surgical (unipolar, bipolar, harmonic scalpel, etc.) devices that operate with a foot control are used. The Gemini Surgical Control & Display System integrates the electro-surgical devices into a central system that uses a single Master Foot Control to activate the devices.

The SurgiClear smoke evacuation activation unit is indicated for use during laparoscopic cases to automatically remove the smoke/steam/debris resulting from the use of electro-surgical instruments.

The system is intended for use in hospitals or outpatient clinics.

Prescription Use YES  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use NO  
(Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)  
*Carlaue Bruehl for Melkerison*  
**(Division Sign-Off)**

**Division of General, Restorative,  
and Neurological Devices**

**510(k) Number** K051831