

K090306

SECTION 5

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

REGULATORY AUTHORITY

Safe Medical Devices Act of 1990, 21 CFR 807.92

JUN 18 2009

COMPANY NAME/CONTACT

Alan Curtis
Aragon Surgical, Inc.
1810 Embarcadero Road, Suite B
Palo Alto, CA 94303

NAME OF DEVICE

Trade Name:	Aragon Surgical RF System Laparoscopic (L2) Instrument
Common Name:	Electrosurgical System
Device Product Code:	GEI
Classification Name:	Electrosurgical Cutting and Coagulation Device and Accessories (21 CFR 878.4400)
Device Panel:	General Surgery/Restorative Devices
Device Classification:	Class II

PREDICATE DEVICES

- Aragon Surgical RF System (K081312)
- LiagSure™ Atlas Laparoscopic Sealer/Divider (K010013)
- Valleylab LigaSure Vessel Sealing System (K981916)

DEVICE DESCRIPTION

The Aragon Surgical Laparoscopic Instrument(L2) is provided as a sterile, single use device. The device is capable of vessel sealing, blunt dissection, grasping and dividing tissue enclosed within its jaws during open and laparoscopic procedures. The device is designed to be used with the Aragon Surgical RF Generator (K081312) and creates vessel ligation by the application of bipolar electrical RF energy and tissue division with a cutting blade.

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INDICATION FOR USE STATEMENT

The Aragon Surgical Laparoscopic Instrument (L2) is a dedicated bipolar electrosurgical instrument intended for use in general surgery and gynecologic laparoscopic surgical procedures where ligation and division of vessels is desired. The instrument create a seal by the application of bipolar electrosurgical RF energy (coagulation) to vascular structure (vessels) interposed between the jaws of the device. A cutting blade is actuated for the division of tissue.

The indications for use include general laparoscopic procedures, (including urologic, vascular, thoracic, and thoracoscopic), and gynecological laparoscopic procedures where ligation and division of vessels is performed. These procedures include: vaginal hysterectomies, Nissen fundoplication, colectomy, adhesiolysis, bowel resection, and oophorectomy etc., or any procedure where vessel ligation (cutting and sealing), tissue grasping, and dissection is performed.

The device can be used on vessels up to and including 7mm and bundles as large as will fit in the jaws of the instrument.

The Aragon Surgical Laparoscopic Instrument has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use the system for these procedures.

SUBSTANTIAL EQUIVALENCE COMPARISON

Comparison to Predicate Devices

The technological characteristics and indications for use of the Aragon Surgical L2 Instrument are similar to those of the cited predicate electrosurgical devices, as well as the similar RF Systems distributed by other manufacturers. These devices are equivalent in terms of design, materials, principal of operation, and product specifications. Any differences between the Aragon Surgical device and the predicate devices do not raise new issues regarding safety or effectiveness.

PERFORMANCE DATA

Results of bench and pre-clinical evaluations were used to demonstrate that the Aragon Surgical L2 Instrument is substantially equivalent to the predicate devices and meets design, safety, and effectiveness criteria.

CONCLUSION

Based on the design, materials, function, intended use, and pre-clinical evaluation, the Aragon Surgical L2 Instrument is substantially equivalent to the devices currently marketed under the Federal Food, Drug and Cosmetic Act. Sufficient data were obtained to demonstrate that the device is substantially equivalent to the predicate devices and raises no new safety or effectiveness issues. Therefore, safety and effectiveness are reasonably assured, justifying 510(k) clearance for commercial sale.

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JUN 18 2009

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Aragon Surgical, Incorporation
% Mr. Alan Curtis, RAC
Vice President, Regulatory/Clinical & Quality Affairs
1810 Embarcadero Road, Suite B
Palo Alto, California 94303

Re: K090306

Trade/Device Name: Aragon Surgical RF L2 Instrument
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: June 5, 2009
Received: June 9, 2009

Dear Mr. Curtis:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing

Page 2-Mr. Alan Curtis

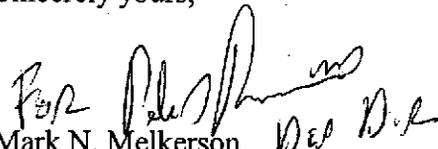
practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to

<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,


Mark N. Melkerson
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION 4

INDICATIONS FOR USE STATEMENT

510(k) Number: _____

Device Name: Aragon Surgical RF System-L2 Instrument

Indications for Use:

The Aragon Surgical Laparoscopic (L2) Instrument is a dedicated bipolar electrosurgical instrument intended for use in general surgical and gynecologic laparoscopic procedures where ligation and division of vessels is desired. The instruments create a seal by the application of bipolar electrosurgical RF energy (coagulation) to vascular structure (vessels) interposed between the jaws of the device. A cutting blade is actuated for the division of tissue.

The indications for use include general laparoscopic procedures, (including urologic, vascular, thoracic, and thoracoscopic), and gynecological laparoscopic procedures where ligation and division of vessels is performed. These procedures include: vaginal hysterectomies, Nissen fundoplication, colectomy, adhesiolysis, bowel resections, and oophorectomy etc., or any procedure where vessel ligation (cutting and sealing), tissue grasping, and dissection is performed.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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510(k) Number K090306