JUL 1 1 2011

SECTION 5

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

REGULATORY AUTHORITY

Safe Medical Devices Act of 1990, 21 CFR 807.92

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 Caiman 5 Laparoscopic 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 (K090306)
- ValleylabLigaSure™ LigaSure 5mm Laparoscopic Sealer and Divider (K031011)
- ValleylabLigaSure™ LigaSure 5mm Blunt Tip Laparoscopic Sealer and Divider (K092879)
- ValleylabLigaSure Vessel Sealing System (K981916)
- ValleyLab ForceTriad RF Generator (K070612)

DEVICE DESCRIPTION

The Aragon Surgical Caiman 5 Laparoscopic Instrument 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 (K093075) and creates vessel ligation by the application of bipolar electrical RF energy and tissue division with a cutting blade.

The Aragon Surgical Lektrafuse RF Generator is designed to be used with Aragon Surgical RF instrumentation only. The Aragon Surgical Lektrafuse RF Generator is not compatible with any other handheld RF surgical instrumentation.

INDICATION FOR USE STATEMENT

The Aragon Surgical Caiman 5 Laparoscopic 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 instrument creates a seal by the application of bipolar electrosurgical RF energy to vascular structures (vessels) interposed between the jaws of the device. A cutting blade is actuated for the division of tissue.

Indications for use include general laparoscopic procedures, including urologic, vascular, thoracic, and thoracsocopic, and gynecological laparoscopic procedures where ligation and division of vessels is performed. These procedures include: laparoscopically assisted vaginal hysterectomies, Nissen fundoplication, colectomy, adhesiolysis, oophorectomy etc.

The Aragon Surgical Caiman 5 Laparoscopic Instrument can be used on vessels up to and including 7mm, and tissue bundles as large as will fit in the jaws of the instrument.

The Aragon Surgical Lektrafuse RF System has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures and should not be used for these procedures.

SUBSTANTIAL EQUIVALENCE COMPARISON

Comparison to Predicate Devices

The technological characteristics and indications for use of the Aragon Surgical Caiman 5 Laparoscopic Instrument are similar to those of the cited predicate electrosurgical devices, as well as the similar RF Systems distributed commercially 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 Lektrafuse RF Generator and Caiman 5 Laparoscopic Instrument are 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 Lektrafuse RF Generator and Caiman 5 Laparoscopic Instrument are 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Aragon Surgical, Inc.
% Mr. Alan Curtis
3617 Scott Street
San Francisco, California 94123

JUL 11 2011

Re: K110824
Trade/Device Name: Aragon Caiman 5 Laparoscopic Instrument, Model 50136
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: June 29, 2011
Received: July 5, 2011

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

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 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/MedicalDevices/Safety/ReportaProblem/default.htm 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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
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 Lektrafuse RF System-Caiman 5 Laparoscopic Instrument

Indications for Use:

The Aragon Surgical Caiman 5 Laparoscopic 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 instrument creates a seal by the application of bipolar electrosurgical RF energy to vascular structures (vessels) interposed between the jaws of the device. A cutting blade is actuated for the division of tissue.

Indications for use include general laparoscopic procedures, including urologic, vascular, thoracic, and thoracsocopic, and gynecological laparoscopic procedures where ligation and division of vessels is performed. These procedures include: laparoscopically assisted vaginal hysterectomies, Nissen fundoplication, colectomy, adhesiolysis, oophorectomy etc.

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The Aragon Surgical Lektrafuse RF System has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures and should not be used for these procedures.

(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

510(k) Number K110824