K093075

SECTION 5

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

REGULATORY AUTHORITY

JAN 21 2010

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 Teleo 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/L2 Instrument (K090306)

DEVICE DESCRIPTION

The Aragon Surgical RF Systems consists of two components: the Aragon Surgical Generator and the Aragon Surgical Teleo Instrument. The Aragon Teleo Instrument is provided as sterile and is intended for single use. The device is capable of vessel sealing, blunt dissection, grasping and dividing tissue enclosed within its jaws.

INDICATION FOR USE STATEMENT

The Aragon Surgical Teleo Instrument is a dedicated bipolar electrosurgical instrument intended for use in general surgery and gynecologic procedures where ligation and division of vessels is desired. The instrument creates 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 surgical procedures (including urologic, vascular, thoracic, and thoracoscopic), and gynecologic surgery 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.

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 Teleo 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

Technological Characteristics

The technological characteristics of the Aragon Surgical Teleo Instrument are identical to those of the cited predicate electrosurgical device, K090306. This device is equivalent in terms of design, materials, and principal of operation. The modification between the Aragon Surgical Teleo Instrument and the predicate device does not raise new issues regarding safety or effectiveness.

Indications for Use

Substantial equivalence is also supported for the Aragon Surgical Teleo Instrument by the predicate devices cleared for general surgery and gynecologic procedures where ligation and division of vessels is desired.

CONCLUSION

Based on the design, materials, function, intended use, and pre-clinical evaluation, the Aragon Surgical Teleo Instrument is substantially equivalent to devices currently marketed under the Federal Food, Drug and Cosmetic Act. In addition, the Aragon Surgical Teleo Instrument raises no new safety or effectiveness issues. Therefore, safety and effectiveness are reasonably assured, justifying 510(k) clearance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

JAN 21 2010

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

Re: K093075
Trade/Device Name: Aragon Surgical RF System Teleo Instrument
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: January 8, 2010
Received: January 11, 2010

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,

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: **K093075**

Device Name: Aragon Surgical RF System Teleo Instrument

Indications for Use:

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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)

FOR M. MELKERSON
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093075