K111845

Espiner Medical Ltd.
Traditional 510(k)
For the Espiner Tissue Retrieval System

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510(k) Summary

This 510(k) Summary is submitted in accordance with 21 CFR Part 807, Section 807.92.

Submitter's Name:

Espiner Medical Ltd

SEP 26 2011

Submitter's Address:

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Establishment Registration Number:

Still to be established

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Date Prepared:

15th August 2011

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Traditional 510(k)

For the Espiner Tissue Retrieval System

510(k) Summary

Device Classification Information:

Regulation Number	Device Name	Device Class	Product Code	Classification Panel
876.1500	Laparoscope, General & Plastic Surgery	Class 2	GCJ	General & Plastic Surgery

Device Trade Name:

The Espiner Tissue Retrieval System

Device Common Name:

The Espiner Sac or E Sac

Note: An accessory to the device is the 'Espiner introducer sleeve'. It is also a class II device.

Intended Use:

The Espiner Tissue Retrieval System consists of a family of impervious sacs which are sterile single use devices that can be used alone or with a dedicated introducer system for the encapture and removal of an organ, tissue or fluid from the body cavity during laparoscopic surgery.

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Summary of Substantial Equivalence:

The predicate device family is the same product (not similar but identical) already approved with a 510(k) (K982073). Espiner Medical Ltd is the original manufacturer of the product family that is currently approved and being distributed in the United States by the Anchor Products Company.

A comparison is presented in the table below:

Property	New Device: Espiner Tissue Retrieval System	Anchor Espiner Tissue Retrieval System
Device Manufacturer	Espiner Medical Ltd	Anchor Products Company
Device Trade Name	The Espiner Tissue Retrieval System	Anchor Espiner Tissue Retrieval System
510(K) Number	N/A	K982073
Product Code	GCJ	GCJ
Device Common Name	The Espiner Sac or E Sac	Anchor Espiner Tissue Retrieval Pouch
Device Classification name	Laparoscope, General & Plastic Surgery	Laparoscope, General & Plastic Surgery
Device Classification	Class II	Class II
Intended Use	The Espiner Tissue Retrieval System consists of a family of impervious sacs which are sterile single use devices that can be used alone or with a dedicated introducer system for the encapture and removal of an organ, tissue or fluid from the body cavity during laparoscopic surgery	The Anchor Espiner Tissue Retrieval System is a sterile disposable pouch that can be used with a dedicated introducer system for the encapture and removal of an organ, tissue or fluid from the body cavity during laparoscopic surgery

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Device Description:

The Espiner Tissue Retrieval System consists of a family of impervious sacs which are sterile single use devices that can be used alone or with a dedicated introducer system for the encapture and removal of an organ, tissue or fluid from the body cavity during laparoscopic surgery.

Technological Characteristics:

A comparative review of the Espiner Tissue Retrieval System with the predicate devices found that the technological characteristics, performance and principle of operation were substantially equivalent (identical).

Performance/Physical Data:

Bench testing demonstrated that the safety and effectiveness of the TFT Espiner Tissue Retrieval System is equivalent (identical) to the predicate devices.

Safety and Effectiveness:

The Espiner Tissue Retrieval System utilises similar technology currently found in legally marketed predicate devices. Based on testing and comparison with the predicate devices, the Espiner Tissue Retrieval System indicated no adverse indications or results. It is our determination that the Espiner Tissue Retrieval System is safe, effective and performs within its design specifications and is substantially equivalent (identical) to the predicate device.

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

Espiner Medical Limited
% Compliance Solutions (Life Sciences) Ltd.
Mr. Edwin Lindsay
116 Almond Road, Cumbernauld
Glasgow, United Kingdom G673LW

SEP 26 2011

Re: K111845
Trade/Device Name: The Espiner Tissue Retrieval System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: June 18, 2011
Received: June 29, 2011

Dear Mr. Lindsay:

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

Espiner Medical Ltd.

Traditional 510(k)
For the Espiner Tissue Retrieval System

K 111845

Indications for Use

510(k) Number (if known):

Device Name: The Espiner Tissue Retrieval System

Indications for Use:

The Espiner Tissue Retrieval System consists of a family of impervious sacs which are sterile single use devices that can be used alone or with a dedicated introducer system for the encapture and removal of an organ, tissue or fluid from the body cavity during laparoscopic surgery.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

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

510(k) Number K111845