

## 5. 510(k) Summary

JUN 14 2013

**Date Prepared:** March 15, 2012

**Device Trade Name:** Modulap Loop

**Common Name:** Unipolar endoscopic coagulator-cutter

**Submitter:** ATC Technologies Inc.  
30B Upton Drive,  
Wilmington, MA 01887

**Contact Person:** John Gillespie (consultant)  
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**Classification:** Coagulator-Cutter, Endoscopic, Unipolar (and accessories) 21 CFR 884.4160, Product code KNF, Class II

**Intended Use:** The Modulap Loop is intended for the amputation of the uterus during laparoscopic supracervical hysterectomy and for resection of pedunculated subserosal (abdominal) myomas.

It is not intended for use in hysteroscopy or for contraceptive coagulation of the fallopian tubes.

### Description of Device

The Modulap Loop is a 5 mm laparoscopic instrument. It consists of a standard insulated monopolar electro-surgical probe, with a flexible wire loop as its distal tip, and a sliding sheath constructed of insulating material. The wire loop is insulated except for a central approximately 1 inch cutting area. The device is a single-use sterile, disposable device. It is compatible with standard electro-surgical generators, and associated cables.

### Summary of Technological Characteristics vs. Predicate

The Modulap Loop and the Predicate device (Lina Gold Loop, K070315) are both Monopolar electro-surgical electrode with loop style tip and sliding sheath; sized to pass through 5 mm laparoscopic trocar; and compatible with standard electro-surgical generators. Their indications for use are equivalent, and other technological characteristics such as design, materials, performance, anatomical sites, energy used, human factors, biocompatibility, sterility, electrical safety, mechanical safety and standards met are the same or equivalent.

**Test Data**

Testing including performance, reliability, materials property testing, biocompatibility, packaging validation and electrical safety testing was performed which supports that the Modulap Loop is equivalent to the predicate with regard to safety and effectiveness.

**Substantial Equivalence**

Based on the Indication for Use, technological characteristics, performance testing, and comparison to its predicate device we conclude that the Modulap Loop has been shown to be substantially equivalent to a legally marketed predicate device and is safe and effective for its intended use.



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

June 14, 2013

ATC Technologies, Inc.  
% Mr. John Gillespie  
Consultant  
Clover Medical  
79 Haven Street  
DOVER MA 02030

Re: K121343  
Trade/Device Name: Modulap Loop  
Regulation Number: 21 CFR§ 884.4160  
Regulation Name: Unipolar endoscopic coagulator-cutter and accessories  
Regulatory Class: II  
Product Code: KNF  
Dated: May 17, 2013  
Received: June 7, 2013

Dear Mr. Gillespie:

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" (21 CFR 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,

Herbert P. Lerner -S

for

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~~Benjamin R. Fisher, Ph.D.~~

Director

Division of Reproductive, Gastro-Renal,  
and Urological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

#### 4. Indications for Use Statement

##### Indications for Use

510(k) Number (if known): K121343

Device Name: Modulap Loop

##### Indications for Use:

The Modulap Loop is intended for monopolar electrosurgical coagulation/cutting during laparoscopic surgery. It is indicated for the amputation of the uterus during supracervical hysterectomy and for resection of pedunculated subserosal (abdominal) myomas.

It is not intended for use in hysteroscopy or for contraceptive coagulation of the fallopian tubes.

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Prescription Use \_\_\_\_\_ 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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert  Lerner -S

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