MAR 20 2000

K994319

VIII. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

A. Submitter's Name

1. Address

ATC Technologies, Inc.
80 Cummings Park
Woburn, Massachusetts 01801

2. Phone Number

(781) 939-0725

3. Contact Person

Paul C. Kierce,
President

4. Summary Preparation Date

December 19, 1999

B. Device Name

1. Trade/Proprietary Name

Modulap®

2. Common/Usual Name

Disposable Unipolar Electrosurgical Probes and Disposable Unipolar Electrosurgical Inserts

3. Classification Name

General and Plastic Surgery Electrosurgical Cutting and Coagulation Device and Accessories

C. Predicate Devices

Modulap Reusable Unipolar Electrosurgical Inserts and Modulap Reusable Unipolar Electrosurgical Attachments

D. Device Description

1. Function

When used in conjunction with a legally-marketed irrigation pump, irrigant bag or bottle, suction source, electrosurgical generator and suction/irrigation trumpet valve, the Candidate Devices provide irrigation, suction and electrosurgical cutting and coagulation capabilities to the operative site during general laparoscopic surgical procedures.

2. Scientific Basis

Provides electrosurgical cutting and coagulation to the surgical site during general laparoscopic surgical procedures by communicating the high-frequency electric current generated by a legally-marketed electrosurgical generator to the operative site.

3. Significant Physical/Performance Characteristics

a) Design

Sterile, disposable.

b) Materials

Information regarding the materials from which the Candidate Devices are constructed is proprietary.

c) Physical Properties

Not applicable.

E. Intended Use Statement

1. Disease/Conditions

The Candidate Devices are intended for irrigation, evacuation of body fluids, and electrosurgical cutting/coagulation during general laparoscopic surgical procedures, (e.g. laparoscopic cholecystectomy, appendectomy and herniorrhaphy). They are not intended for use in hysteroscopy or for contraceptive coagulation of the Fallopian tube.

2. Patient Population

The Candidate Devices are intended for use in patient populations eligible for monopolar electrosurgical treatment via general laparoscopic surgical procedures.

F. Technological Characteristics Summary

The Candidate Devices consist of a stainless steel cannula and connector used to communicate electrosurgical, suction, and irrigation capabilities to the operative site during laparoscopic surgical procedures.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 20 2000

ATC Technologies, Inc.
c/o Marian Harding Cochran, Esq.
1034 Lincoln Street
Hollywood, Florida 33019

Re: K994319
Trade Name: Modulap®
Regulatory Class: II
Product Code: GEI
Dated: December 19, 1999
Received: December 22,1999

Dear Ms. Cochran:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Steven Rhodes

James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K994319

IX. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): Not yet assigned.

Device Name: Modulap® Disposable Unipolar Electrosurgical Probes and Disposable Unipolar Electrosurgical Inserts

Indications for Use:

The Candidate Devices are indicated for use in patients eligible for monopolar electrosurgical treatment via general laparoscopic surgical procedures.

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

Prescription Use XX OR Over-The-Counter Use___

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K994319