FEB 1 1999

K984275

Exhibit #1
3 Pages

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is:_____

1. **Submitter's Identification:**

Joshua Urueta, M.D.
President/CEO
Amada Surgical Inc.
7010 S. Santa Clara Avenue
Tucson, AZ 85706

Date Summary Prepared:

November 24, 1998

2. **Name of the Device:**

The Golden Tip™ Electro-Surgical Probe

3. **Predicate Device Information:**

The Golden Tip™ Electro-Surgical Probe is "substantially equivalent" to: 1) Valley Lab Coated Electrodes, K#962044, 2) Davis-Bayonet ™ Electrodes, K#96402, 3) MegaDyne ElectroSurgery Electrode, K#903302, MegaDyne Medical Products, Inc.

4. **Device Description:**

The Golden Tip™ Electro-Surgical Probe is a conventional electrosurgical instrument to which is applied electrical energy in the form of a radio-frequency signal for purposes of cauterizing or cutting during a surgical procedure.

5. **Intended Use:**

The Golden Tip™ Electro-Surgical Probe is an electrocautery electrode and intended for use in open surgical procedures.

6. **Comparison to Predicate Devices:**

The Golden Tip™ Electro-Surgical Probe is substantially equivalent to electro surgical probes currently marketed by manufacturers holding 510(k) clearance. Predicate devices currently marketed include electro-surgical electrodes with various coatings such as silicone and/or a nickel-phosphorous matrix. The Golden Tip™ Electro-Surgical Probe intended to be marketed by Amada Surgical Inc. offers a gold and teflon coating.

Discussion of Similarities and Differences:

The Golden Tip™ Electro-Surgical Probe is similar in intended use, principle of operations, etc. to the MegaDyne Medical Products, Inc. Electrosurgery electrode, K#903302. Intended use of the MegaDyne device is "Electrocautery Electrode for Surgical Procedures." The Golden Tip™ coated electrode blade is gold and teflon coated and is substantially equivalent to the MegaDyne teflon coated electrode.

The Golden Tip™ is similar in structural design to the MegaDyne probe with the exception that the Golden Tip™ uses a gold and teflon coated tip. This process allows for better electrical conductivity to cut flesh and cauterize, while allowing easy passage of the blade through the flesh without sticking and permitting easier cleaning of the blade while reducing surgery time.

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

Testing information demonstrating safety and effectiveness of the Golden Tip™ Electro-Surgical Probe in the intended environment of use is supported by testing that was conducted in accordance with the FDA October 1993 Draft "510(k) Guideline for General Surgical Electrosurgical Devices", which outlines performance requirements.

None of the testing demonstrated any design characteristics that violated the requirements of the Reviewer Guidance or resulted in any safety hazards.

1. Electrode Functional Testing:

   Functional tests were performed on beef steaks, chicken breasts and beef liver steaks in the laboratory. All Golden Tip™ Electro-Surgical Probes performed properly and no electrode damage occurred at recommended power levels.

2. Assembly Testing:

All Golden Tip™ Electro-Surgical Probes are assembled properly into the following electrosurgical pencils:

Valley Lab, Aspen Labs, Birtcher, Conmed, and other pencils (handswitch universal) that utilize the standard 3-terminal receiver. All have exhibited an appropriate removal force. The force required to separate the Electrode Tip from the Electrode Shaft have met performance requirements satisfactorily.

We certify that the Golden Tip™ Electro-Surgical Probe is designed to meet all applicable requirements of the ANSI/AAMI HF-18/1993 specifically, Section 4.2.5.4, American National Standard for Electrosurgical Devices. Electrode insulation was tested at both low frequency and radio frequency typical of electrosurgical generators. The electrical insulation testing passed all test requirements.

8. **Discussion of Clinical Tests Performed:**

Pre-clinical performance was tested on dogs, using surgical procedures and testing specifications were met.

9. **Conclusions:**

The Golden Tip™ Electro-Surgical Probe, is substantially equivalent in intended use, design, material and technology as the MegaDyne ElectroSurery Electrode. Thus, when compared to the predicate device, the Golden Tip™ Electro-Surgical Probe does not incorporate any changes in intended use, method of operation, material or design that could affect safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 1999

Ms. Susan D. Goldstein-Falk
Official Correspondent
Amada Surgical, Inc.
c/o MDI Consultants, Inc.
55 Northern Boulevard, Suite 200
Great Neck, New York 11021

Re: K984275
Trade Name: The Golden Tip™ Electro-Surgical Probe
Regulatory Class: II
Product Code: GEI
Dated: November 24, 1998
Received: November 30, 1998

Dear Ms. Goldstein-Falk:

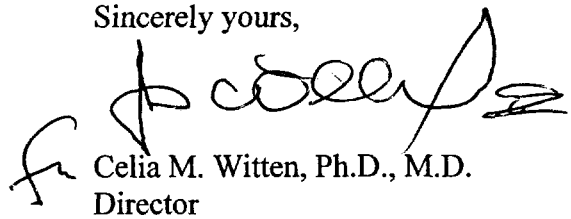
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): _____

DEVICE NAME: The Golden Tip™ Electro-Surgical Probe

INDICATIONS FOR USE:

The Golden Tip™ Electro-Surgical Probe is an electrocautery electrode and intended for use in open surgical procedures.

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

Concurrent of CDRH, Office of Device Evaluation (ODE)

Prescription Use X 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 K984275