

JUL -1 1996

1. IDENTIFICATION OF SUBMITTER

Submission of 510(K) approval is made by:
Endo-Tech Ltd., Inc.

1.1 Establishment Registration Number

1056537

1.2 Mailing Address

4040 Nine McFarland Drive
Suite 800
Alpharetta, Georgia 30201

2. DEVICE NAME

Endo-Tech, Ltd., Inc. Laparoscopic Unipolar Tips

3. IDENTIFICATION OF PREDICATE

We believe that these devices are substantially equivalent to Electrosurgical Attachments sold by American Hydro-Surgical.

3.1 Classification Name

Laparoscope, Gynecologic(and accessories) or
Coagulator, Laparoscopic, Unipolar(and accessories)

3.2 Common/Usual Name

Laparoscopic Unipolar Tips

3.3 Classification

Laparoscopic Unipolar Tips would most likely have been reviewed by the FDA Obstetrics and Gynecological Device Classification Panel. We believe that this device classification code is OBHET , a class II device under regulation number 884.1720 or, code OBHFG, a class II device under regulation number 884.4160.

4. DEVICE DESCRIPTION

4.1 Function

The Laparoscopic Unipolar Tips will be threaded into the Endo-Tech, Ltd., Inc. Endo-Aid (K#930756) and will be used during Laparoscopic procedures. These tips will be used by a range of surgeons for various abdominal procedures in a hospital operating room environment.

4.2 Physical and Performance Characteristics

Human Function

User Range: Adult, Male and Female
 Left and Right Handed
 5 to 95%ile Surgeons

Removable sheath made for easier cleaning
Adjustable insulation sheath covers and exposes tips
Ratcheting sheath stays in fixed position until adjusted
Removable tip threads off for easier cleaning
Labeled tubing to reduce confusion
Labeling includes instructions and identification
Case and label colors approved by Endo-Tech, Ltd.
Attractive aesthetics
Reusable, Autoclaved.

Technical Function

Drop proof from 45 inch height onto tile floors
Operating temperature range 40 to 110⁰-F
Storage temperature range -40 to 150⁰ F
Hospital solvent resistant: water, alcohols, blood, saline solutions
USP Class VI
stainless steel tips
Threaded connections accept Endo-Tech Ltd., Aspiration-Irrigation Device, K#930756
Case material is nonconductive
reduction of component parts
High reliability design and documentation methods for FDA approval

Production Function

Production quantities of 5,000 units first year
Total production run of 25,000 units
Simplified tooling design
Tooling and parts designed for manufacture by approved vendors
Qualification testing for tips and connections
Production engineered for low cost assembly
Package designed for efficient storage and handling
Packaging labeled for inventory controls

4.3 COMPONENTS

The Laparoscopic Unipolar Tips consist of the following components:

Threaded adapter (Male)
Thread on probe and stainless tip (Female: Spatula, L Hook, J Hook, and Needle)
Insulation Sheath for Electrosurgical Tips (Ratcheting)

5. INTENDED USE

The Laparoscopic Unipolar Tips will serve as accessories to the Endo-Tech, Ltd, Inc., Endo-Aid, which is an Aspiration- Irrigation Device. These tips will thread into the laparoscopic irrigation and aspiration control handle. The tips will be used during laparoscopic procedures and electro-surgical procedures.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Most features of the laparoscopic unipolar tips are functionally identical to the predicate products; exceptions include dimensions/weight, colors, and sheath design summarized here.

6.1 DIMENSIONS/WEIGHT

Characteristics	Endo-Tech	American Hydro-Surgical
Tip Overall	15.7" x .63" x .63"	13.5" x .68" x .68"
Tip Internal Diameter	.154"	.154"
Tip Internal Diameter (Electrosurgical)	.1"	.1"
Tubing Length	13"	11"
Tubing Length (Electrosurgical)	15"	12.5"
Thread	3/8-16AWC	3/8-16AWC
Weight Overall	.8oz	.8oz

6.2 COLORS

Characteristics	Endo-Tech	American Hydro-Surgical
Threaded Adapter	white	white/black/clear
Threaded Probe	white	white
Threaded Probe (Electrosurgical)	black	black
Insulated Sheath	black	black

6.3 SHEATH DESIGN

The insulation sheaths of both companies are designed to be adjustable to the desired length of the surgeon. The difference lies in the ability of the Endo-Ltd, laparoscopic unipolar tips to adjust and stay in a fixed position until moved by the surgeon. American Hydro-Surgical devices do not have the ratcheting mechanism.

7. CONCLUSION DRAWN FROM DATA SUPPORTING EQUIVALENCE DETERMINATION

The Endo-Tech Ltd., Inc. laparoscopic unipolar tips are designed to be equivalent to the electrosurgical attachments that are manufactured by American Hydro-Surgical. These tips are to be used in conjunction with the Endo-Aid(K#930756) during laparoscopic procedures. These tips, along with the Endo-Aid, enables hydro-dissection of tissue, aspiration and irrigation of fluids, lavage, blunt dissection, smoke evacuation, and the delivery of electrosurgical energy.

8. CONCLUSION

This concludes the section.