NOV 17 1999

K992931

510(k) Summary
Link Technology, Inc.
Non-Stick Bipolar Forceps

Submitter (Consultant) Name and Address
Morningstar Consulting Group, Inc.
P. O. Box 219
Indian Hills, CO 80454

Submitter (Consultant) Contact Person
Kevin Morningstar, Senior Consultant
phone: (303) 697-8198
fax: (303) 697-7907

Manufacturer Name and Address
Link Technology, Inc.
4001 Discovery Drive, Suite 390
Boulder, CO 80303

Manufacturer Contact Person
Jonathan Thorne, CEO
phone: (303) 444-1949
fax: (303) 4446237

Common, Classification & Proprietary Names

Common Name:	electrosurgical electrode
Classification Name:	electrosurgical cutting and coagulation device and accessories
Proprietary Name:	non-stick bipolar forceps

Predicate Devices
Ball Tip Electrode, Fusion Technologies, Inc., K970987
Midas Touch Bipolar Electrodes, ITI Medical Technologies, Inc., K982705

Device Description
The Link Technology Non-Stick Bipolar Forceps electrode is an electrosurgical tool in the typical tweezers configuration. The forceps are constructed with stainless steel and coated with an electrical insulator. The uninsulated forceps tip is plated with a proprietary metallurgical alloy. The forceps are compatible with standard OEM (original equipment manufacturer) electrosurgical generators and bipolar electrode cables.

Indications for Use
This product is intended to facilitate grasping and manipulation of soft tissue and blood vessels and provide electrocautery in surgical procedures.

Technological Characteristics Comparison

This claim of substantial equivalence to the Fusion Ball Tip electrode is specifically in relation to the proprietary non-stick metal, and the claim of substantial equivalence to the ITI Midas Touch Bipolar Forceps is in relation to non-stick bipolar forceps in general.

The proprietary non-stick metal used in the Fusion Ball Tip Electrode is the same as that plated onto the tip of the Link Technology Non-Stick Bipolar Forceps Electrode. Therefore, the characteristics of the material which comes into contact with tissue during surgical use, such as non-stick properties, biocompatibility, and thermal and electrical conductivity, are identical.

In general design, configuration and intended use, the Link Technology Non-Stick Bipolar Forceps Electrode is substantially equivalent to the ITI Midas Touch Bipolar Forceps, except as explained above regarding the choice of surface material. The two forceps designs utilize different surface materials in order to achieve the desired non-stick performance. Otherwise they are interchangeable.

Performance and Safety

The biological safety of the Non-Stick Bipolar Forceps has been defined through the selection of materials which demonstrate the appropriate levels of biocompatibility for its clinical use. This demonstration is based upon choosing materials that have an established history of safe use in similar medical devices, literature research, and biocompatibility studies that meet the standards outlined in ISO 10993-1.

The Non-Stick Bipolar Forceps are re-usable surgical devices, provided non-sterile to the user. The Instructions for Use provide instructions for the cleaning, decontamination, and sterilization of the device before each use. The instructions for reprocessing of the device will be validated before the device is marketed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Link Technology, Inc.
c/o Mr. Kevin Morningstar
President and Senior Consultant
Morningstar Consulting Group, Inc.
P.O. Box 219
Indian Hills, Colorado 80454

Re: K992931
Trade Name: Non-Stick Bipolar Forceps
Regulatory Class: II
Product Code: GEI
Dated: August 28, 1999
Received: August 31, 1999

Dear Mr. Morningstar:

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

Enclosure

510(k) Number (if known): K992931

Device Name Link Technology Non-Stick Bipolar Forceps

Indications for Use:

The Link Technology Non-Stick Bipolar Forceps product is intended to facilitate grasping and manipulation of soft tissue and blood vessels and provide electrocautery in surgical procedures.

(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 General, Restorative Devices
510(k) Number K992931

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96