EXHIBIT # 1

OCT 1 8 2004

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: K042608

1. **Submitter's Identification:**

Tecno Instruments (Pvt) Ltd.
316-C Small Industrial Estate
Sialkot-51340 (PAKISTAN)
Tel: +92 432 552723 / 552681

Date Summary Prepared: October 11, 2004

2. **Name of the Device:**

Tecno Reusable Bipolar Cables, Model (190-100 and 190-110)

3. **Common or Usual Name:**

Electrosurgical Bipolar Cable

4. **Predicate Device Information:**

Quantum Instruments Corp. all models

5. **Device Description:**

All bipolar forceps are connected to ES Generator through ES Cables. There is a male and female end termination on these cables, usually male end termination is connected with the ES Generator, while female end termination is connected with the bipolar forceps. The cable is made of Silicone material which is flexible as well as autoclavable. The silicone cable can be further classified as single-core, two-core and three-core cable depending on the intended use. The usual length of an electrosurgical cable is 3 meters.

6. **Intended Use:**

An electrosurgical cable is a device intended to connect Electrosurgical Generator with electrosurgical cutting & coagulation devices.

7. Comparison to Predicate Devices:

The Tecno ES Cables are substantially equivalent the Quantum Instruments Corp. ES Cables, as well as other legally-marketed electrosurgical cables. It has same standard fitting on the ES generator side and same fitting on the instrument side.

The Tecno ES Cables is similar to the Quantum predicates in its intended use, safety and efficacy, design specification, power source and performance criteria. The Tecno device may differ from the predicates in color and size. However, these differences raise no issues of safety or effectiveness.

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

Testing was conducted in accordance with ANSI/AAMI HF18-2001 and IEC 60601-2-2 (3 ed), Medical Electrical Equipment – Part 2-2: Particular requirements of high frequency surgical instruments on Bipolar Cables. Test results concluded that cable meets the requirement of safety and effectiveness

9. Discussion of Clinical Tests Performed:

Not Applicable

10. Conclusions:

Testing performed on Techno instrument Bipolar cables indicated it is safe and effective and performs as well as the predicate device when used in accordance with the instruction for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 18 2004

Tecno Instruments (PVT) Ltd.
C/o Mohan Ratanchandani
MDI Consultants, Inc.
55 Northern Boulevard
Suite 200
Great Neck, New York 11021

Re: K042608
Trade/Device Name: Tecno Reusable Bipolar Cables, Model (190-100 and190-110)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: September 23, 2004
Received: September 24, 2004

Dear Mr. Ratanchandani:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

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

Enclosure

Exhibit B

510(k) Number (if known): K042608

Device Name Tecno Reusable Bipolar Cables, Model (190-100 and 190-110)

Indications For Use: Tecno Reusable Bipolar cables model (190-100 and 190-110) are intended to connect Electrosurgical Generator with electrosurgical cutting & coagulation devices.

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K042608

Prescription Use YES
(Per 21 CFR 801 Subpart D)

OR

Over-The Counter Use_____
(21 CFT 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)