5. 510(K) SUMMARY

JAN 13 2006

EVER PROSPEROUS INSTRUMENT, INC.

Models: ***TRACTION SYSTEM, DIGIT-TRAC 930***

510K: K052453

- Manufacturer : EVER PROSPEROUS INSTRUMENT, INC.
  Registration # 1000635107
  Owner ID# 9075179
- Address : 4F, No.2 & 4F, No.4, Alley 59, Lane 42, Ming-Chuan Road, Hsin-Tien, Taipei Hsien, Taiwan
- Official Correspondent: Dr. Jen, Ke-Min
  No.58, Fu-Chiun Street, Hsin Chu City,
  30067, Taiwan
- Classification name: *Powered Traction Equipment*
- Product Code: *ITH, Class II*
- *Regulation Number:* *890.5900*
- Proprietary name: ***TRACTION SYSTEM, DIGIT-TRAC 930***
- Common name of device: *POWERED TRACTION EQUIPMENT*
- Predicate Device: *1.* ***K862846***
  TEC VARI-TRAC II TRACTION UNIT
  *2.****K993919***
  DYNATRON 900

Statement of Intended Use: The **TRACTION SYSTEM, DIGIT-TRAC 930** is intended for medical purpose for use in conjunction with traction accessories, such as belts and harnesses, to exert therapeutic pulling forces on the patient's body.

⚠ **Caution**: **The device is for "prescription-use only."**

Comparison to Predicate Devices: The **TRACTION SYSTEM, DIGIT-TRAC 930** has been carefully compared to legally marketed devices with respect to intended use and technological characteristics. In addition, EMC (EN 60601-1-2) and Electrical Safety (EN 60601-1) testing have been done to validate the electrical safety of the device. The comparison and validation results presented in this 510k notification to the FDA that means the subject device is substantially equivalent to predicated devices and are safe and effective in its intended use.

We believe that the TRACTION SYSTEM, DIGIT-TRAC 930 is substantially equivalent to the predicate devices, i.e., TEC VARI-TRAC II TRACTION UNIT in K862846 and DYNATRON 900 in K993919, and the data provided support the safety and effectiveness of TRACTION SYSTEM, DIGIT-TRAC 930 for the intended uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 13 2006

Ever Prosperous Instrument, Inc.
c/o Dr. Ke-Min Jen
ROC Chinese-European Industrial Research Society
No. 58, Fu-Chiun Street
Hsin Chu City, Taiwan 30067

Re: K052453
Trade/Device Name: Digit-Trac 930 Traction System
Regulation Number: 21 CFR 890.5900
Regulation Name: Equipment, Traction, Powered
Regulatory Class: II
Product Code: ITH
Dated: December 25, 2005
Received: January 03, 2006

Dear Dr. Jen:

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) 276-0120. 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/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Acting Director
Division of General, Restorative and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

Indications for Use

510(k) Number: **K052453**

Device Name: EVER PROSPEROUS INSTRUMENT, INC.
TRACTION SYSTEM, DIGIT-TRAC 930

INTENDED USE

The TRACTION SYSTEM, DIGIT-TRAC 930 is intended for medical purpose for use in conjunction with traction accessories, such as belts and harnesses, to exert therapeutic pulling forces on the patient's body.

Prescription Use ___√___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(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,
and Neurological Devices

510(k) Number K052453