JAN 30 1998

K973814

VIII. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

A. Submitter's Name

1. Address

   Valley West, Inc.
   P. O. Box 678
   Highway 6 North
   Meridian, TX 76665

2. Phone Number

   (254) 435-2306

3. Contact Person

   C. Kenneth French, President

4. Summary Preparation Date

   January 13, 1998

B. Device Name

1. Trade/Proprietary Name

   Trump-It II™
   and
   Magnum 250

2. Common/Usual Name

   Trumpet Valve Suction-Irrigation Handpiece

3. Classification Name(s)

   General and Plastic Surgery Laparoscope and Accessories

C. Predicate Device(s)

In terms of safety, effectiveness, and intended use, the Candidate Device is substantially-equivalent to the following legally-marketed device ("Predicate Device"):

Device Name:	Nezhat-Dorsey Hydro-Dissection System & Accessories
Manufacturer:	American Hydro-Surgical Instruments, Inc.
510(k) Number:	K951086
Substantial Equivalence Date:	3/16/95

D. Device Description

1. Function

When used in conjunction with a legally-marketed irrigation pump, irrigant bag or bottle, and legally-marketed suction source, the Candidate Device provides suction and irrigation to the surgical site during general laparoscopic procedures.

2. Scientific Basis

Provides pinpoint suction and irrigation to the surgical site during laparoscopic procedures by combining a hand-held trumpet valve suction-irrigator and laparoscopic probe.

3. Significant Physical/Performance Characteristics

a) Design

Sterile, disposable. For single use only.

b) Materials

The materials from which this device is constructed are proprietary.

c) Physical Properties

Not Applicable.

E. Intended Use Statement

1. Disease/Conditions

The Candidate Device is intended for use in the treatment of disease conditions via general laparoscopic surgical procedures.

2. Patient Population

The Candidate Device is indicated for use in patient populations eligible for treatment via general laparoscopic surgical procedures.

F. Technological Characteristics Summary

The Candidate Device consists of a hand-held trumpet valve suction-irrigator designed to provide pinpoint suction and irrigation to the surgical site during general laparoscopic procedures. This device is designed for use with legally-marketed irrigation pumps, irrigant bags and bottles, and legally-marketed suction sources.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 30 1998

Ms. Julie H. Byerly
Regulatory Affairs Consultant
Valley West, Incorporated
C/O Accureg, Incorporated
300 NW 82nd Avenue, Suite 402
Plantation, Florida 33324

Re: K973814
Trade Name: Trump-It II and Magnum 250
Regulatory Class: II
Product Code: GCJ
Dated: January 13, 1998
Received: January 15, 1998

Dear Ms. Byerly:

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 requirements , 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 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

IX. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K973814
Device Name: Trump-It II™ or Magnum 250

Indications for Use:

The device is indicated for use in patients eligible for treatment via general laparoscopic surgical procedures.

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

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K973814

Prescription Use (XX) OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)