

MAY 12 1999

Valley West, Inc.

K 990447

TRADE SECRET

510 (k) SUMMARY

This 510(k) summary of 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: _____

Submitted by: C. Kenneth French
President
Valley West, Inc.
Hwy 6, North
Meridian, Texas 76665

Telephone #: (254) 435-2306
Facsimile #: (254) 435-2226

Date Prepared: 19 November 1998

Establishment Registration Number: Valley West, Inc. is located at Hwy 6, North, Meridian, Texas 76665. We are registered with the Food and Drug Administration as Establishment Number 1645369.

Classification Name: Pressure Infusor for an IV bag
21 CFR § 880.5420 (1997)

Laparoscope, Gynecologic and Accessories
21 CFR § 884.1720 (1996)

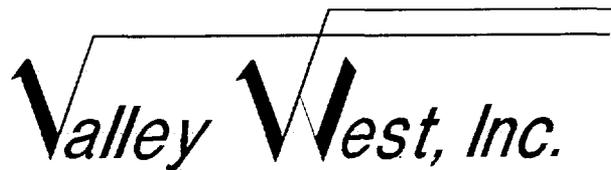
Jet Lavage
21 CFR § 880.5475 (1997)

Common/Usual Name: Pressurized Irrigation/Infiltration Pump

Proprietary Name: 1000 Pressure Infusor

Indication for Use: General surgical fluid irrigation and infiltration.

Device Description: The principles of operation and technology incorporated in the 1000 Pressure Infusor are equivalent to pressurized irrigation systems, which use compressed nonflammable gases within a closed bladder (inflatable cuff to apply direct pressure externally to a bag of fluid for infusion of fluids).



Substantial Equivalence Claim: The principles of operation and technology incorporated in the Valley West, Inc. 1000 are similar to other irrigation devices with the function to pressurizing bags of fluid which the FDA has found to be substantially equivalent to pre-amendment devices as outlined below.

Product: MX820-5 Pressure Infusor 500cc / MX820-10 Pressure Infusor 1000cc
Manufacturer: Medex, Inc.
510(k) Number: K800560
Substantial Equivalence Date: 29 April 1980

Product: Nezhat-Dorsey Hydro-Dissection Universal Bag Squeezer
Manufacturer: Davol, Inc.
510(k) Number: K953574
Substantial Equivalence Date: 29 September 1995

Product: Automatic Surgical Irrigation Pump/Autocuff
Manufacturer: Alton Dean Medical, Inc./Spartamed, Inc.
510(k) Number: K922286
Substantial Equivalence Date: Unknown

Product: Niagara Pump, 3.0 Liter High Volume
Manufacturer: Cabot Medical Systems
510(k) Number: K924530
Substantial Equivalence Date: 05 February 1993

Product: Big Bag 3000
Manufacturer: Byron Medical
510(k) Number: K973133
Substantial Equivalence Date: 10 September 1997

Product: Lapro Flow 3000
Manufacturer: ASSC
510(k) Number: K980089
Substantial Equivalence Date:

-end of summary-



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY 12 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. C. Kenneth French
Valley West, Incorporated
Highway 6, North
Meridian, Texas 76665

Re: K990447
Trade Name: 1000 Pressure Infusion Sigmacon 1000
Regulatory Class: II
Product Code: FRN
Dated: November 19, 1998
Received: February 12, 1999

Dear Mr. French:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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.

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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) 594-4692. 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>".

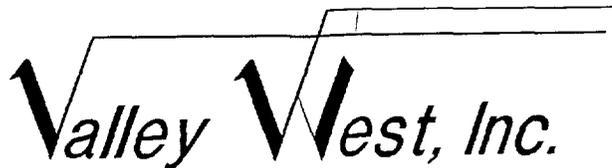
Sincerely yours,



f/

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



510(k) Number (if known): _____

Device Name: 1000 Pressure Infusor for General Fluid Irrigation/Infiltration

Indications for Use:

The 1000 Pressure Infusor indications for use are general surgical fluid irrigation and infiltration.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

Over-the-Counter Use _____
(Optional format 1-2-96)

Patricia Cicentini

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number K980447