SEP 21 2001

K011343
1of1

510(k) SUMMARY as required by 807.92 (c)

APPLICANT

NAME:	LH Medical Products, Inc.
ADDRESS:	301 E. Arrow Hwy, Suite 104 San Dimas, CA 91773
PHONE:	877-592-0523
FAX:	909-592-8596
E-MAIL:	lhoffstetter@lhmedicalproducts.com
REGISTRATION #:	9041241
ACTIVITY OF APPLICANT:	Initial Distributor
CONTACT PERSON:	Lonnie Hutson Vice President
PHONE:	877-592-0523
FAX:	909-592-8596
E-MAIL:	lhutson@lhmedicalproducts.com
NAME OF DEVICE:	
Trade Name:	LH 500 Enteral Feeding Gravity Bag Set
Common Name:	Enteral Bag w/Gravity Set
Classification Name:	Tubes, Gastrointestinal (And Accessories)
PRODUCT CODE:	KNT
MANUFACTURER:	Weihai Medical Polymer (Group) Co., LTD No. 35 Yantai (W) Rd.,Weihai, Shandong 264209 Peoples Republic of China
PREDICATE DEVICE:	Novartis (Compat) 199216 Vinyl Bag with pre-attached Enteral Delivery Gravity Set

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 21 2001

Mr. Lonnie Hutson
Vice President
LH Medical Products, Inc.
301 E. Arrow Hwy., Suite 104
SAN DIMAS CA 91773

Re: K011343
Trade/Device Name: LH500 Enteral Bag Gravity Set
Regulation Number: 21 CFR §876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: 78 KNT
Dated: August 18, 2001
Received: August 21, 2001

Dear Mr. Hutson:

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 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 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 one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K011343

Device Name: LH 500 Enteral Feeding Gravity Bag Set

Indications For Use:

This device is intended to temporarily hold and deliver by gravity, liquid nutrition formulas to an enteral access device (a feeding tube).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K011343