

Attachment 1

510(k) Summary of Safety and Effectiveness

Med-Rx® Extension Sets

Submitter Information:

Bill C.K. Lim
Manager of Regulatory Affairs
Benlan Inc.
2760 Brighton Road
Oakville, Ontario
Canada L6H 5T4

Phone 905 829-5004
Fax 905 829-5006

Date 510(k) Summary Prepared: March 3, 1999

Name/Classification of the Device:

Classification Name:	Intravascular Administration Set
Common Name:	I.V. Extension Sets
Propriety Name:	Med-Rx® Extension Set
Classification/Panel	Class II in CFR 880.5440, Intravascular Administration Set Panel: General Hospital (GH)

Identification of the Legally Marketed Device to which the Submitter Claims Equivalence:

The Med-Rx® Extension sets are substantially identical in materials, packaging, sterilization, and intended use to Medex Extension Sets, MX454-FL, MX448-L36 and 536040 manufactured by Medex Inc.

Description of the Subject Device:

The Med-RX® Extension Sets consist mainly of a fluid delivery tubing provided with capped luer connectors at the proximal ends. The extension sets can thus be connected to an I.V. administration sets whereby extending infusion site(s) of a primary I.V. catheter. The fluid delivery tubing can vary in lengths as well as bore sizes, i.e. standard bore, mini-bore and micro-bore.

The extension sets may include pinch or slide clamps.

Intended Use of the Subject Device:

The extension sets are intended for use in I.V. therapy when extended fluid path is required in the administration of I.V. solutions or drugs. Benlan Inc. does not cause or promote new intended uses for these devices.

Technological Characteristics of the Subject Device:

There are no differences in the characteristics of the subject device and the predicate(s).



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 25 1999

Mr. Bill C.K. Lim
Manager, Regulatory Affairs
Benlan, Incorporated
2760 Brighton Road
Oakville, Ontario
CANADA L6H 5T4

Re: K990777
Trade Name: Med-Rx® Extension Set
Regulatory Class: II
Product Code: FPA
Dated: June 18, 1999
Received: June 22, 1999

Dear Mr. Lim

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

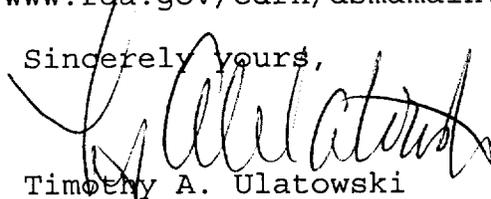
Page 2 - Mr. Lim

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) 594-4692. 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,



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

Enclosure

K 990777

**Med-Rx® Extension Sets
Attachment 3**

510(k) Number (if known) _____

Device Name: **Med-Rx® Extension Sets**

Indications for Use:

These extension sets are sterile, single use, medical devices intended for use in I.V. therapy when extended fluid path is required for fluid or drug administration. Benlian Inc. does not cause or promote new intended uses for these devices.

(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 Dental, Infection Control,
and General Hospital Devices

510(k) Number K 990777

Prescription Use _____
(per 21 CFR 801.109)

OR

Over the Counter Use _____

(Optional Format 1-2-96)