K983994

JAN 8 1999

510(k) SUMMARY

DATE OF APPLICATION:	1st August 1998
APPLICANTS ADDRESS:	Owen Mumford Inc 849 Pickens Industrial Drive Suite 14 Marietta GA 30062 USA
CONTACT:	Mr Robert Shaw
POSITION:	Director
TEL: **FAX:**	770 425 5138 770 426 5365
REGISTRATION No:	1058602
TRADE NAME	Unifine
COMMON NAME:	Insulin syringes
CLASSIFICATION NAME:	Piston Syringe
CLASS:	2
CLASSIFICTION PANEL:	General Hospital
PANEL CODE:	80 HO
CFR NUMBER:	880.5860
SUBSTANTIAL EQUIVALENCE	The product is substantially equivalent to the Omnican Insulin Syringe manufactured and distributed by B Braun (K962084).

DEVICE DESCRIPTION

The Unifine range if syringes are identical to that of the Omnican range of syringes manufactured by B Braun. The syringes are manufactured, packed and sterilised by B Braun and supplied to Owen Mumford for sale or distribution. No re-packaging, reworking or modifications are made to the syringes or packaging by Owen Mumford. The are supplied in three sizes (0.3ml, 0.5ml & 1ml) in boxes of 100. The individual syringes are supplied in peel pouches and are sterilised using Ethylene Oxide.

STATEMENT OF INTENDED USE

The device is for the subcutaneous injection of insulin.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 8 1999

Mr. Robert E. Shaw
Owen Mumford, Incorporated
849 Pickens Industrial Drive
Suite 14
Marletta, Georgia 30062-3165

Re: K983994
Trade Name: Unifine
Regulatory Class: II
Product Code: FMF
Dated: November 6, 1998
Received: November 9, 1998

Dear Mr. Shaw:

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 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). 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) 594-4692. 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" (21CFR 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/dsma/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

510(k) Number: **Not Known**

Device Name: **Unifine**

Indications for Use:

The Unifine range of Syringes is designed for the subcutaneous injection of insulin.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ **OR** **Over-The-Counter Use** ✓

(Per 21CFR 801.109)

Patricia Cuenca

(Division Sign-Off)
Division of Dental Infection Control,
and General Hospital Devices
510(k) Number K983994