

DEC - 4 1997

510k SUBMISSION**UNIFINE PENTIPS****SUMMARY**

Submitted by:

Robert E. Shaw
Owen Mumford, Inc.
849 Pickens Industrial Dr.
Suite 14
Marietta, GA 30062

Device Name: Unifine Pentip
Substantial Equivalence: Becton Dickinson Microfine
Classification Name: Hypodermic Single Lumen Needle

Owen Mumford has been marketing the Unifine Pentip throughout Europe for over 12 months without any adverse customer reports. The product has also been sold throughout Europe by the original manufacture under the name "Braun Omnican."

DESCRIPTION

The Owen Mumford Unifine Pentip is visually and mechanically extremely similar to the BD Microfine Pentip to which substantial equivalence is claimed.

INTENDED USE

The Unifine Pentip are intended for the subcutaneous injection of drugs from prefilled cartridges used in conjunction with variable dose delivery systems such as Pen Injectors. Its intended use is substantially equivalent to that of the BD Microfine.

OPERATIONAL

The principle operation and design concepts of the Unifine Pentip are substantially equivalent to that of the BD Microfine Pentip.

PERFORMANCE

Performance of the Unifine Pentip, when compared to the BD Microfine, is substantially equivalent.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Robert E. Shaw
Vice President
Owen Mumford, Incorporated
849 Pickens Industrial Drive, Suite 14
Marietta, Georgia 30062

DEC - 4 1997

Re: K973899
Trade Name: Unifine Pentips
Regulatory Class: II
Product Code: FMI
Dated: October 14, 1997
Received: October 14, 1997

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 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 (Pre-market 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 requirement, 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

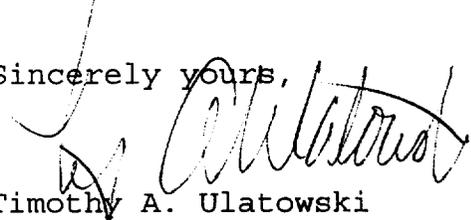
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through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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) 594-4618. 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

K973899

510(k) Number (if known): Not known

Device Name: UNIFINE PENTIPS

Indications for use:

The Unifine Pentip is single use, disposable hypodermic single lumen needle designed for use with multidose injection devices that use prefilled cartridges.

The protective paper is removed from the Pentip which is then screwed onto the device cartridge housing and then used in the prescribed manner.

One of the main uses of the Pentip is for use with pen Injectors for the delivery of insulin which is supplied in the form of prefilled cartridges. The patient places a fresh Pentip needle onto the Pen Injector, dials a dose, inserts the Pentip into the skin and delivers the dose.

Concurrence of CDRH, Office of Device Evaluation (ODE).

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

510(k) Number K973899

Prescription Use OR Over-the-Counter Use

(Per 21CFR 801.109)

(Optional Format 1-2-96)