K983974

Owen Mumford, Inc.

849 Pickens Industrial Drive
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Marietta, Georgia 30062-3165

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510(K) SUBMISSION

AUTOPEN 3ml

SUMMARY

Submitted By:

Robert E. Shaw
Owen Mumford, Inc.
849 Pickens Industrial Dr.
Suite 14
Marietta, GA 30062-3165

Device Name:	Autopen® 3ml
Substantial Equivalence:	Autopen® 1.5ml K895890
Classification Name:	Introducer, Syringe Piston

DESCRIPTION:

Autopen® is cylindrical in shape, approximately 165mm x 15mm including cover. The Owen Mumford 3ml Autopen® is based upon a proven design marketed in both Europe since 1988 and the United Sates since 1989 when 510(k) approval was granted for the Owen Mumford 1.5ml Autopen® K895890. There has been no change at all to the design concept since then, and only minor design improvements otherwise in response to customer feedback and continuous improvement as required of a company with ISO 9001, FDA GMP and EN 46001 status. These changes are essentially cosmetic such as:

A) A one piece cap instead of a three piece cap to facilitate assembly.

B) The cartridge housing was modified to a one piece rather than a two piece to piece to improve durability.

C) The cartridge housing can now accommodate a 3.0ml cartridge as opposed to the 1.5ml and is made of one piece rather than 2 separate components in the Owen Mumford 1.5ml Autopen® K895890.

D) The printing on the dose selector was changed to improve visibility.

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INTENDED USE:

The delivery of insulin products using a variable dose pen for insulin dependent diabetics. The Owen Mumford Autopen® 3ml is a non-sterile, automatic, subcutaneous injection device which uses a replaceable 3ml insulin cartridge (supplied by others) held within the body of the device. Maximum delivery is 42 units in 2 unit increments. An automatic drive system is used to displace the insulin from the cartridge through sterile disposable pen needles.

OPERATIONAL:

The internal and operational mechanisms of the Autopen® 3ml are mechanically identical to it substantially equivalent Autopen® 1.5ml. The only difference is one of scale to operate the larger diameter 3.0ml cartridge.

PROFORMANCE:

The Autopen® 3ml has been tested to draft ISO/TC 84/WG3 standard "pen injectors of medical use". As confirmed by ISO test results, Autopen® is safe and effective when used as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 21 1998

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

Re: K983974
Trade Name: Owen Mumford 3ml Autopen®
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 (if known):

Device Name: Autopen 3ml

Indications For Use:

The delivery of insulin products using a variable dose pen for insulin dependent diabetics. The Owen Mumford 3ml Autopen is a non-sterile automatic subcutaneous injection device which uses a replaceable 3ml insulin cartridge held within the body of the device. An automatic drive system is used to displace the insulin from the cartridge through a sterile disposable needle.

(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_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

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

510(k) Number_____