

NOV 10 1998

K993385
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AUTOJECT®2
NON-FIXED NEEDLE

10. 510(K) SUMMARY

Submitted by:

Robert Shaw
Director/ Vice President
Owen Mumford Incorporated
849 Pickens Industrial Drive
Suite 14
Marietta
GA 30062

Tel: 770 425 5138

Device Name: Autoject®2 (Non-Fixed Needle type)
Substantial Equivalence: Autoject®2 (Fixed Needle type)
Classification Name: Syringe Needle Introducer

Owen Mumford have successfully been marketing the Autoject® 2 device throughout the world for several years. The Autoject® 2 (Non-Fixed Needle type) is simply a member of the same family of devices. The product has been widely accepted as an excellent medium for the administration of drugs via automatic injection throughout the EEC, Israel, Canada and Australia

510(K) SUBMISSION
AUTOJECT® 2
NON-FIXED NEEDLE

10. 510(K) SUMMARY

DESCRIPTION

A hand-held general purpose mechanical injection device for the sub-cutaneous injection of Insulin and other approved medicines.

The Autoject® 2 (Non-fixed Needle type) is visually identical to and has the same area of intended use i.e. for the sub-cutaneous injection of medicament, as the current 510(K) approved Autoject® 2 (Fixed Needle type) device to which substantial equivalence is claimed. The firing mechanisms of both devices are identical, the only difference being the design changes necessary for the syringe housing to accommodate and make safe the use of Non-Fixed needle type syringe.

INTENDED USE

Both the Autoject® 2 (Non-Fixed Needle type) and the Autoject® 2 (Fixed Needle type) devices are intended for the sub-cutaneous injection of drug treatments.

OPERATIONAL

The principle, design concepts and applications of the Autoject® 2 (Non-Fixed Needle type) and the Autoject® 2 (Fixed Needle type) devices are substantially equivalent.

PERFORMANCE

Performance of both devices is substantially equivalent, the difference in ability to empty the contents of the syringe is due to the limitations of the type of syringe, i.e. Fixed or Non-fixed needle syringes. Due to a small amount of residual drug being left in the space between the syringe and the needle hub the dose accuracy results show a slightly lower level of performance. However, if this residue is taken into account the performance of both types of devices are extremely close.

NON-CLINICAL TRIAL DATA.

The correspondence included in section 9 of this submission, referencing the study carried out in Australia, clearly indicates the success of the device when used in the application of the medicament



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

NOV 10 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K993385
Trade Name: Autojet®2 (Non-Fixed Needle type) Syringe
Needle Introducer
Regulatory Class: II
Product Code: KZH
Dated: September 24, 1999
Received: October 8, 1999

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 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

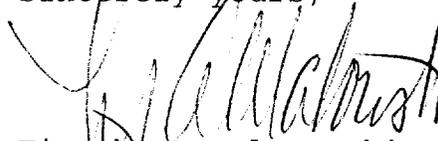
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the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, 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" (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

510(k) Number (if known): K993385

Device Name: Autoject® 2, Non-fixed Needle

Indications For Use:

A general purpose hand-held mechanical device intended for the subcutaneous injection of Insulin and other approved drugs. The device is designed for use with disposable 1ml non-fixed needle syringe and to accommodate self use in the home by the patient in order to aid and support compliance with the recommended treatment regime.

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

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

Prescription Use _____
(per 21 CFR 801.109)

Patricia Ciccone OR
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K993385

Over-The-Counter Use

(Optional Format 1-2-96)