Title:	Autoject II For Glass Syringe Special 510(k) Submission
Section:	6.0 – 510(k) Summary
Revision:	01
Date:	September 2012

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SECTION 6.0

OCT 15 2012

510(k) SUMMARY

(AS REQUIRED BY SECTION 807.92(c))

Applicants Name & Address:

Mr. Darren Mansell

Owen Mumford Ltd.
Brook Hill
Woodstock,
Oxfordshire
OX20 1TU
United Kingdom

Device Classifications:

Common Name:	Autoject® II for glass syringe
Classification Name:	Syringe Needle Introducer
CFR Number:	880.6920
Panel:	80.HO General Hospital
FDA Classification:	II

Legally Marketed Device To Which This Document Claims Substantial Equivalence:

- **Predicate Device:** Autoject® II for glass syringe
- **Predicate Device 510(k) Number:** K013362
- **Predicate Device Manufacturer:** Owen Mumford Ltd
  Brook Hill
  Woodstock
  Oxfordshire
  OX20 1TU
  England
- **Predicate Device Manufacturer FDA Device Establishment Registration Number:** 8021764

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510(k) SUMMARY

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Predicate Device Details:

Common Name:	Autoject® II for glass syringe
Classification Name:	Syringe Needle Introducer
Class:	II
Classification:	General Hospital
Panel Code:	80
CFR Number:	880.6920
510(k) Number:	K013362

Description Of The Device & Intended Use:

The 'Autoject® II for glass syringe' is composed of simple plastic injection moulded parts and stainless steel springs.

The device is a non-sterile, handheld mechanical device intended for self-administered, subcutaneous delivery of an FDA approved drug. The device is designed for use with 1ml fixed needle pre-filled glass syringe, for use in the home to aid, support and reduce patient trauma due to the treatment regimen. It has been developed to provide a safe and simple procedure to the patient.

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Technological Characteristics – Compared To Predicate Device:

Test/Characteristic	Submission Device Autoject II for glass syringe (modified)	Predicate Device Autoject II (K013362)
Drug	FDA approved drug	FDA approved drug
Primary container	1ml fixed needle pre-filled glass syringe	1ml fixed needle pre-filled glass syringe
Patient target group	Those requiring administration of an FDA approved drug	Those requiring administration of an FDA approved drug
Dose system	One injection per syringe	One injection per syringe
Depth of penetration	4-12mm	4-12mm
Accessories	1ml fixed needle pre-filled glass syringe	1ml fixed needle pre-filled glass syringe
Maximum force required to load the device (Newtons)	20.0N	20.0N
Force required to activate the device (Newtons).	4.0-10.0N	4.0-10.0N
Force required to release the safety mechanism (Newtons).	1.0-2.5N	1.0-2.5N
Overall length of device (millimetres)	190	190
Overall width of device – at widest point (Millimetres)	25	25
Syringe handling forces – maximum stress exerted on syringe	82 – 160 MPa	125 - 250 MPa
Base materials	Identical to predicate device	Identical to predicate device

The summary table above shows the comparison of the technical characteristics between the submission device and the predicate device. Additionally, the raw materials for each component were compared (see Section 9.2). It was noted that all of the materials are the same for each component on both devices. Furthermore, the mode of operation is exactly the same for each device, the only difference is the fact that the submission device incorporates a modified 'damper' component, which is intended to improve the handling of the syringe inside the device.

The technical characteristics are exactly the same between the modified device, and the predicate device with the exception of the syringe handling forces. The maximum stress exerted on the syringe is lower on the modified device. This is a direct result of the modified damper component on the modified device, which improves the syringe handling capabilities of the device, handles the syringe better and therefore helps to reduce the stress exerted on the syringe during normal use. The reason why a range is shown for the syringe handling force in the table above is explained further in Section 10.2.

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Non-Clinical Performance Data:

A number of tests have been performed proving that the device operates safely and effectively, and displays performance characteristics equivalent to those of the predicate device:-

- Verification of needle exposure (exposed needle length).
- Verification of delivered volume.
- Verification of dose delivery time.
- Verification that the 'end of injection indicator' is visible on the device

Furthermore, Finite Elemental Analysis (FEA) testing was initiated to confirm that the modified damper component in the submission device conferred reduced stresses on the syringe, compared to the damper component on the predicate device. The FEA studies detailed the interaction of the damper on the syringe flanges as the device is activated and the syringe travels through the device.

Clinical Performance Data:

Clinical performance data has not been submitted, and is therefore not included in this Special 510(k) document.

Conclusions From Performance Data:

The results from the testing noted above (see Section 10.0) demonstrate that the submission device shows equivalent performance to the predicate device. Furthermore the results help to show that the submission device is safe, performs as per its intended use, and will pose no additional risk to a patient, compared to the predicate Autoject® II device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Owen Mumford, Limited
C/O Mr. Darren Mansell
Regulatory Affairs Manager
Brook Hill, Woodstock
Oxfordshire OX20 1TU
United Kingdom

OCT 15 2012

Re: K122837
Trade/Device Name: Autoject® II for glass syringe
Regulation Number: 21 CFR 880.6920
Regulation Name: Syringe Needle Introducer
Regulatory Class: II
Product Code: KZH
Dated: September 13, 2012
Received: September 17, 2012

Dear Mr. Mansell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

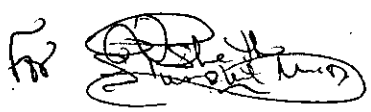
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K122837

SECTION 5.0

INDICATIONS FOR USE STATEMENT

510(K) Number: TBC

Device Name: 'Autoject® II for glass syringe'

Indications For Use:

The Autoject® II for glass syringe is a non-sterile fully automatic injection device. The device utilises a 1ml fixed needle pre-filled glass syringe. The Autoject® II for glass syringe is capable of subcutaneous delivery of an FDA approved drug.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

10/12/12

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

510(k) Number: K122837