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K111467

FEB - 9 2012

510(k) Summary: Flexi-Q DV Auto-injector

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Date prepared: January 5, 2012

Trade Name: Flexi-Q DV Auto-injector

Classification name: Syringe needle introducer

Class: II

Panel identification: General Hospital

Product code: KZH

Regulation number: 880.6920

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Predicate Devices: Mixject Dispensing Pin with Detachable Vial Holder and Pre-attached Needle from Medimop Medical Projects Ltd, Ra'anana, Israel, cleared under 510(k) **K001293** and **Autoject 2** from Owen Mumford USA Inc, Marietta, GA, USA, cleared under 510(k) **K013362.**

Device description:
The Flexi-Q DV Auto-injector (also called: FUDAI DV)) is designed to allow people with or without minor dexterity problems (or with a help of a care giver) to aspirate a drug in solution form from a standard 13mm vial and automatically inject themselves subcutaneously with the drug.

The device is comprised of the following parts:

- **Housing:** The outer shell/covering of the device. The Housing which encloses and protects the inner components including the syringe, is designed to be used while held with one hand and provides the user with visibility of the solution/ drug before, during and after injection via a window.

- **Syringe:** A standard 1mL long glass syringe is assembled within the Housing. The syringe includes a staked ½" 27G needle and an elastomeric syringe piston. The syringe is marked with a single graduation line indicating the dose volume to be aspirated and delivered (any dosage between 0.3 to 1.0mL is possible; e.g., 0.3 or 0.4 or 0.5 or 0.6 etc. up to 1.0mL). i.e., different Flexi-Q Auto-injector versions will be available, each for a single dosage volume, and according to physician prescription, the patient will use the Flexi-Q Auto-injector version specifically marked for his/her prescribed dose volume. The "single dose – single device" Flexi-Q auto-injectors are illustrated in page 11-13, Figure I.
  The syringe needle is used to penetrate the Vial Adaptor septum (for solution/reconstituted drug aspiration) and then to administer the subcutaneous injection to the patient.

- **Needle Shield:** The needle shield covers the needle before injection. When depressed against the skin, the shield "unlocks" the Trigger Button to allow activation and injection. After the injection is completed, the shield locks in place, keeping the needle from being accessible and helping protect the user from accidental needle stick injury.

- **Plunger Rod:** A rigid rod that is connected to the syringe piston and protrudes out of the Auto-injector's Housing. The Plunger Rod is used to aspirate the solution/reconstituted drug into the syringe and adjust the volume to be injected to the predefined dosage.

- **Trigger Button (Red INJECT Button):** This button enables the user to activate the injection process after is has been unlocked by the user pressing the shield against the skin at the injection site. Once pressed the device advances the injection needle into the subcutaneous tissue followed by injection of the drug.

- **One Vial Adaptor (Gray Connector):** The Sterile, Single use Vial Adaptor functions as a connector between the Auto-injector and the drug vial and provides a fluid path to enable aspiration of the drug. The syringe needle penetrates a septum (assembled inside the Vial Adaptor) made of thermoplastic elastomer while a plastic spike (part of the Vial Adaptor) penetrates the vial stopper. While attached to the Auto-injector, the Vial Adaptor conceals the Needle Shield and thus preventing inadvertent activation.

  In certain cases when additional vial may be used (per drug prescription), additional sterile vial adaptor(s), may be used.

Indications for Use:
The Flexi-Q DV Auto-injector is **indicated** for the transfer and automated subcutaneous injection of FDA approved drugs and biologics in compatible vials.

The Flexi-Q DV Auto-injector is **intended** for use in the home environment by the patient or care-giver after training by a Health Care Professional.

Substantial Equivalence:
The Flexi-Q DV Auto-injector has the same intended use and the same principle of operation as the **Mixject Dispensing Pin with Detachable Vial Holder and Pre-attached Needle** from Medimop Medical Projects, Ltd, Ra'anana, Israel, cleared **under 510(k) number K001293** and **Autoject 2** from Owen Mumford USA Inc, Marietta, GA, USA, cleared under 510(k) number **K013362** when used together and is therefore substantially equivalent to the predicate devices.

Conclusion:
The evaluation of the Flexi-Q DV Auto-injector does not raise any additional concerns regarding safety and effectiveness and may therefore be considered substantially equivalent to the predicate devices.

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

Mr. Shay Shaham
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ISRAEL 13860

FEB - 9 2012

Re: K111467
Trade/Device Name: Flexi-Q DV Auto-Injector
Regulation Number: 21 CFR 880.6920
Regulation Name: Syringe Needle Introducer
Regulatory Class: II
Product Code: KZH
Dated: January 11, 2012
Received: January 18, 2012

Dear Mr. Shaham:

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.

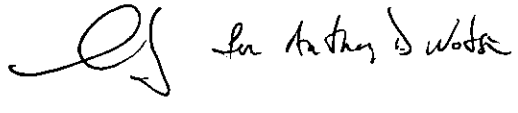
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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

Enclosure

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Indications for Use

510(k) Number (if known): K111467

Device Name: Flexi-Q DV Auto-injector

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The Flexi-Q DV Auto-injector is **intended** for use in the home environment by the patient or care-giver after training by a Health Care Professional.

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)

for RZC feb 9, 2012

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

510(k) Number: K111467