K073476
1 of 2

The Medical House

MAR - 7 2008

MEDICAL HOUSE (ASI) LTD

Pre-Market Notification	**Section 5.0 510(k) Summary**	Revision No: 02
Product: Compact Auto-Safety Injector (CASI)		Effective Date: 05 March 2008

510(k) Summary [As required by 21 CFR 907.92(a)]

A. Submitter Information:

Submitter: Medical House (ASI) Limited
199 Newhall Road
Sheffield, S9 2QJ
United Kingdom

Contact person: Rose Y Guang
Quality, Regulatory Affairs & Operations Director
E-mail: rguang@themedicalhouse.com
Phone: (+) 44 1142 619 011
Fax (+) 44 1142 431 597

Date: March 05 2008

B. Device Information:

Trade/ Proprietary Name: Compact Auto-Safety Injector (CASI)

Common Name: Auto-Injector

Classification Name: Introducer, syringe needle

Predicate Device: Modification to Autoject Mini K000482

Device Description: The CASI is a single-use, automatic, disposable and hidden-needle auto-injector for the self-administration of liquid drug products.

Intended Use: The Compact Auto-Safety Injector (CASI) is indicated for assisting the self-administered subcutaneous injection of fixed doses of FDA approved drug products with viscous liquid formulations, which are presented in standard 1ml long BD Hypak® pre-filled syringes with staked needles. The CASI is primarily intended for home use by patients to aid and support their treatment regime or may be used by Health Care Professionals or caregivers.

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C. Comparison of Required Technological Characteristics

The CASI device applies the same technological characteristics as the predicate device. It is designed similarly to the devices that are currently marketed in the U.S.

The key difference of the CASI is that the syringe needle is retracted into the device following injection, rather than remaining exposed or simply covered as in the predicate device. Due to the technological identity and equivalent indications for use of the CASI device and the predicate device, no additional safety items were identified.

D. Summary and Conclusion of Performance Tests

Extensive design verification, functional and performance testing have been conducted. The information provided in this premarket notification demonstrates that the CASI device is safe and effective for the intended use and is substantially equivalent to the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Rose Y. Guang
Quality, Regulatory Affairs & Operations Director
Medical House (ASI) Limited
199/201 Newhall Road
Sheffield S9 2QJ
UNITED KINGDOM

MAR - 7 2008

Re: K073476
Trade/Device Name: Compact Auto Safety Injector (CASI)
Regulation Number: 21 CFR 880.6920
Regulation Name: Syringe Needle Introducer
Regulatory Class: II
Product Code: KZH
Dated: November 30, 2007
Received: December 10, 2007

Dear Ms. Guang:

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.

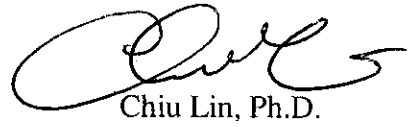
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

The Medical House

MEDICAL HOUSE (ASI) LTD

Pre-Market Notification	**Section 4.0 Indication For Use Statement**	Revision No: 02
Product: Compact Auto-Safety Injector (CASI)		Effective Date: 05 March 2008

510(k) Number: K073476
Device Name: Compact Auto Safety Injector (CASI)

Indications For Use:
The Compact Auto Safety Injector (CASI) is indicated for assisting the self-administered subcutaneous injection of fixed doses of FDA approved drug products with viscous liquid formulations, which are presented in standard 1ml long BD Hypak® pre-filled syringes with staked needles.

The CASI is primarily intended for home use by patients to aid and support their treatment regime or may be used by Health Care Professionals or caregivers.

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND 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)

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

510(k) Number: K073476