

OCT 02 2008

K072587



MEDICAL HOUSE PRODUCTS LTD

Pre-Market Notification	<b>Section 5.0</b> <b>510(k) Summary</b>	Revision No: 01
Product: Auto Safety Injector-2 (ASI-2)		Effective Date: 5 <sup>th</sup> September 2008 ✓

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

**A. Submitter Information:**

Submitter: Medical House Products Limited  
199 Newhall Road  
Sheffield, S9 2QJ  
United Kingdom

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

Date: 5<sup>th</sup> September 2008

**B. Device Information:**

Trade/ Proprietary Name: Auto Safety Injector-2 (ASI-2)

Common Name: Auto-Injector

Classification Name: Introducer, syringe needle

Predicate Device: Compact Auto-Safety Injector (510(k) No: K073476)

Device Description: The ASI-2 is a single-use, automatic, disposable and hidden-needle auto-injector for the self-administration of liquid drug products.

Intended Use: The Auto Safety Injector 2 (ASI-2) is indicated for assisting the self-administered subcutaneous injection of fixed doses of FDA-approved drug products with non-viscous (aqueous) liquid formulations, which are presented in standard 1ml long BD Hypak<sup>®</sup> pre-filled syringes with staked needles. The ASI-2 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 ASI-2 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 between the ASI-2 device and the predicate device is that the ASI-2 device is not specifically intended for viscous liquid formulations.

**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 ASI-2 device is safe and effective for the intended use and is substantially equivalent to the legally marketed predicate device.



OCT 02 2008

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Rose Y. Guang  
Quality, Regulatory Affairs & Operations Director  
Medical House Products Limited  
199 Newhall Road  
Sheffield, S9 2QJ  
UNITED KINGDOM

Re: K082587  
Trade/Device Name: Auto Safety Injector 2 (ASI-2)  
Regulation Number: 21 CFR 880.6920  
Regulation Name: Syringe Needle Introducer  
Regulatory Class: II  
Product Code: KZH  
Dated: September 5, 2008  
Received: September 8, 2008

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 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



MEDICAL HOUSE (ASI) LTD

Pre-Market Notification	<b>Section 4.0 Indication For Use Statement</b>	Revision No: 01
Product: Auto-Safety Injector 2 (ASI-2)		Effective Date: 5 <sup>th</sup> September 2008 <i>✓</i>

510(k) Number:  
Device Name: Auto Safety Injector 2 (ASI-2)

Indications For Use:

The Auto Safety Injector 2 (ASI-2) is indicated for assisting the self-administered subcutaneous injection of fixed doses of FDA-approved drug products with non-viscous (aqueous) liquid formulations, which are presented in standard 1ml long BD Hypak® pre-filled syringes (PFS) with staked needles.

The ASI-2 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)

*[Signature]*  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

510(k) Number:   K082587