

510(k) SUMMARY
*ConfidDose*TM IM Auto-injector

K060389

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Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared:

Pharma-Pen, Inc.
6136 FM 1616
Athens, TX 75752
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JUN - 6 2006

Contact Person: Richard D. Gillespie III, P.E.

Date Prepared: February 6, 2006

Name of Device and Name/Address of Sponsor:

Trade Name: *ConfidDose*TM IM Auto-injector
Name / Address of sponsor: Pharma-Pen, Inc.
6136 FM 1616
Athens, TX 75752
Phone: 1-903-677-5017
Facsimile: 1-903-677-6083

Common or Usual Name: Auto Injector

Classification Name: Introducer, Syringe Needle
Regulation Number: 880.6920
Medical Specialty: General Hospital
Product Code: KZH
Device Class: Class II

Predicate Devices:

- Union Medico Aps.; Personal Injector (K033696),
- Biogen; InvisijectTM Reusable Auto Injector (K032425),
- Pharma-Pen Inc.; *ConfidDose* Auto-Injector (K042557).

Intended Use:

The *ConfidDose*TM IM auto-injector is a semi-automatic injection system intended to be used for the manual transfer, containment and intramuscular injection of liquid drugs and biologics under the direction of a physician. The *ConfidDose*TM IM auto-injector system includes an automatic needle retraction mechanism that is intended to aid in the prevention of accidental needle sticks. The *ConfidDose*TM IM auto-injector system is intended to mask needle insertion, injection and needle withdrawal from patient view.

Technological Characteristics and Substantial Equivalence:

The *Confidose*TM IM auto-injector consists of a syringe cartridge with prefixed needle, power pack housing with spring loaded mechanism to insert a hypodermic needle into a patient to predetermined depth below the skin surface and a window tube with spring-loaded retraction mechanism. It is pressure actuated. Once activated, the device automatically performs all three steps of the injection process, needle insertion, drug injection and needle withdrawal. The *Confidose*TM IM auto-injector is individually packaged and ETO sterilized for single use.

The *Confidose*TM IM auto-injector utilizes a spring-loaded mechanism to insert a hypodermic needle into a patient to predetermined depth below the skin surface and dispense the medication, and includes an automatic spring-loaded retraction mechanism. The same technological characteristics are found in various commercially marketed auto-injectors, which operate on the generally same principle.

In contrast to *Confidose*TM IM auto-injector, the predicate devices (except the *Confidose* auto-injector K042557) do not automatically retract the hypodermic needle after the injection process is completed.

The *Confidose*TM IM auto-injector is substantially equivalent to the other currently marketed auto-injectors, which are referenced above. The *Confidose*TM IM auto-injector and its predicate devices are all Introducer, Syringe Needle products. As described in the substantial equivalency table and supported by the extensive testing performed by the company, the *Confidose*TM IM auto-injector raises no new issues of safety or effectiveness.

Performance Data:

FDA has established no performance standards for this device classification. Performance of the *Confidose*TM IM auto-injector was assessed using applicable sections and methods specified in ISO 11608-1: *Pen-Injectors for Medical Use-Part 1: Requirements and Test Method*. Dose accuracy, dead space, flow rate, injection time / dwell time, reliability (number of activations without failure), accuracy of penetration depth, needle bond strength, absence of leakage, verification of non-coring needle properties, needle penetration force, device actuation force, torque necessary to defeat the safety of the device, verification of syringe markings accuracy, chemical resistance, free fall resistance, environmental stability were assessed. The device met all the requirements and specifications. In all instances, the *Confidose*TM IM auto-injector functioned as intended and the observed results were as expected.

Conclusion

Pharma-Pen, Inc. concludes, based on the information presented herein, that the *Confidose*TM IM auto-injector is substantially equivalent to similar products that have received FDA clearance and are currently legally marketed in the USA.



JUN - 6 2006

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Pharma-Pen, Incorporated
C/O Mr. Jonathan S. Kahn, Esquire
Hogan & Hartson, L.L.P.
555 Thirteenth Street
Washington, D.C. 20004-1109

Re: K060389
Trade/Device Name: ConfiDose™ IM Auto-Injector
Regulation Number: 880.6920
Regulation Name: Syringe Needle Introducer
Regulatory Class: II
Product Code: KZH
Dated: May 16, 2006
Received: May 16, 2006

Dear Mr. Kahn:

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

K060389

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Indications for Use Statement

510(k) Number (if known): _____

Device Name: **Confidose™** IM Auto-injector

Indications for Use:

The **Confidose™** IM auto-injector is a semi-automatic injection system intended to be used for the manual transfer, containment and intramuscular injection of liquid drugs and biologics under the direction of a physician. The **Confidose™** IM auto-injector system includes an automatic needle retraction mechanism that is intended to aid in the prevention of accidental needle sticks. The **Confidose™** IM auto-injector system is intended to mask needle insertion, injection and needle withdrawal from patient view.

Prescription Use
 (Part 21 C.F.R. 801 Subpart D)

AND/OR

Over-The-Counter Use _____
 (21 C.F.R. 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Shubh A. Mehrotra, MD *Anthony Watson* 6/6/04

Division of Anesthesiology, General Hospital,
FDA, Center for Device and Radiological Control, Dental Devices

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