K083457

510(k) SUMMARY

[as required by section 807.92(c)]

FEB 13 2009

General Information

Submitted by:	Haselmeier GmbH Dufourstr. 32 CH-8008 Zurich Switzerland
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Date Prepared:	October 2, 2008

Device Name

Trade Name:	TactiPen
Common Name:	Piston syringe
Classification Number:	880.5860
Product Code:	FMF

Predicate Devices

Haselmeier Pen	K070100	Haselmeier GmbH
Disetronic Pen	K982966	Disetronic Medical System
HumaPen and HumaPen Ergo	K982842	Eli Lilly and Company

Device Description

The TactiPen is a reusable pen-injector designed to provide a method of accurately subcutaneously injecting the desired dose of U-100 insulin from a single lumen hypodermic needle. The device can be used by health professionals or for self-injection by the patient.

The pen-injector uses 3.0-mL cartridges of U-100 insulin and a single use, detachable and disposable needle (supplied separately). The pen injector allows the user to dial the desired dose.

The device is compatible with commercially available pen needles (supplied separately) that comply with: ISO 11608-2:2000 Pen-injectors for medical use - Part 2: Needles - Requirements and test method and 3-mL ISO type A cartridges (supplied separately), which meet ISO 11608-3: 2000 Pen-injectors for medical use - Part 3: Finished cartridges - Requirements and test methods.

Intended Use

The TactiPen is a self injection device intended to deliver a subcutaneous injection of U-100 insulin from a 3-mL cartridge.

Technological Comparison

The TactiPen has similar indications for use and overall function and performs in a similar manner with respect to the Haselmeier Pen, Disetronic Pen, HumaPen, and HumaPen Ergo.

The technological characteristics of the TactiPen and its drug cartridge are the same as product currently legally marketed in the USA.

Performance Data

The TactiPen has been demonstrated to perform as intended.

The TactiPen conforms to the requirements when tested using the methods specified in the ISO Standard, ISO 11608-1:2000, "Pen-injectors for Medical Use – Part 1 Requirements and Test Methods."

Conclusion

Haselmeier concludes based on the information presented that the TactiPen is substantially equivalent to products currently, legally marketed in the USA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 13 2009

Haselmeier GmbH
C/o Mr. Stephen J. Goldner, JD, RAC
President
Regulatory Affairs Associates
30833 Northwestern Highway, Suite 121
Farmington Hill, Michigan 48334-2581

Re: K083457
Trade/Device Name: TactiPen
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: November 20, 2008
Received: November 21, 2008

Dear Mr. Goldner:

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,

Anthony D. Watson for

Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known):	K083457
Device Name:	TactiPen
Sponsor Name:	Haselmeier GmbH
Indications for Use:	The TactiPen is a self injection device intended for the subcutaneous injection of U-100 insulin from a 3-mL cartridge.

Prescription Use ☒ (21 CFR 801 Subpart D) Or Over-The-Counter Use ☐ (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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