K110312

7. Summary of Safety and Effectiveness

JAN 2 6 2012

"510(K) SUMMARY"

Submitted By/
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Date Prepared: January 28, 2011

7.1. Trade/Proprietary Name: Clickfine AutoProtect Pen Needle

7.2. Common/Usual Name: Injection Pen Needle

7.3. Classification Name: Hypodermic single lumen needle

7.4. Classification: FDA has classified Hypodermic single lumen needles in Class II. Final Order was published in the Federal Register on October 21, 1980 after review by the General Hospital and Personal Use Devices Classification Panel.

Panel: 80 Procode: FMI

7.5. Purpose of Submission: To establish the substantial equivalence of the modified Ypsomed Clickfine AutoProtect Pen Needles to the Clickfine Pen Needles cleared for legal marketing in the USA per 510(k) file K102108.

7.6. Substantial Equivalence: The Ypsomed Clickfine AutoProtect Pen Needles are substantially equivalent to the Clickfine Pen Needles (K102108). The equivalence is supported by the attached documentation.

7.7. Device Description

The Ypsomed Clickfine AutoProtect Pen Needles are sterile, non-pyrogenic, single use needles designed to be used with commercially available pen-injectors for the administration of prescribed fluids. Each needle is individually packaged in a sealed protective container with a peel tab. The pen needle is used by peeling back the peel tab and snapping the housing onto the threaded end of the pen-injector. The back end of the cannula punctures the septum of the drug reservoir in the pen-injector. The outer protective cap is then removed. When the injection is needed the needle is inserted into

the chosen site. While inserting the needle into the skin, the safety shield glides into the housing enabling the needle to penetrate the skin barrier and into the subcutaneous tissue. While the safety shield glides into the housing the safety mechanism will be activated. The pen-injector delivers the medicinal product through the needle.

After the injection, in order to remove the needle from the skin, the user moves the pen injector away from the skin. As the pen and needle is moved away from the skin, the safety shield glides back in its initial position, completely covering the needle, where it will remain locked. The safety shield is designed to automatically cover the needle (provide passive protection) to minimize the risk of accidental needle-stick injury. Once the Clickfine AutoProtect pen needle is in the locked mode, it can no longer be used. The red safety lock indicator tells the user that the safety lock has been activated. The needle is detached from the injection device and disposed of in accordance with local regulations. For each subsequent injection, another disposable needle must be used.

7.8. Intended Use

The intended use of the modified device remains the same as the predicate device (Clickfine Pen Needles, K102108):
The Ypsomed Clickfine AutoProtect Pen Needles are intended for the hypodermic injection of fluids into the body when attached to an injection pen.

Additionally, after withdrawal of the pen needle from the body, the attached needle safety shield automatically covers the needle to minimize the risk of accidental needle-stick.

7.9. Technological Characteristics

The Clickfine AutoProtect pen needle is considered substantial equivalent to K102108, Clickfine pen needle, in intended use (intended for use with pen-injectors for the hypodermic injection of fluids) and in the device's operating principles. The addition of the needle safety function does not affect the intended use or alter the fundamental scientific technology of the device but improves the safety of the product.

7.10. Performance and Safety Data

Ypsomed has performed the relevant assessments specified in the following international and internal standards and protocols and confirmed compliance of the modified devices and equivalence to the predicate devices.
The Clickfine AutoProtect pen needles have met the requirements of the relevant sections of the following standards:

- ISO 11608-2:2000 Pen-injectors for medical use – Part 2: Needles – Requirements and test methods
- ISO 9626:1991/Amd.1:2001 Stainless steel needle tubing for the manufacture of medical devices
- ISO 7864:1993 Sterile hypodermic needles for single use
- ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management system
- Seal Integrity of Sterile barrier

- ISO/FDIS 23908 (N156) Sharps injury protection - Requirements and test methods - Sharps protection features for single-use hypodermic needles, catheters, introducers for catheters and needles used for blood sampling
- Simulated Use Studies per FDA Guidance for Industry and FDA Staff - Medical Devices with Sharps Injury Prevention Features, dated August 9, 2005

The verifications have shown evidence that the Clickfine AutoProtect Pen Needles meet the acceptance criteria of these standards. Based on the results it can be concluded that the device performance and safety are acceptable for the product.

7.11. Conclusion

Ypsomed AG concludes based on the information presented that the modified product is substantially equivalent to the current product legally approved in the USA.

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. Andre Sauter
Regulatory Affairs Manager
Quality System & Regulatory Affairs
Ypsomed AG
Brunnmattstrasse 6
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SWITZERLAND CH-3401

JAN 2 6 2012

Re: K110312
Trade/Device Name: Clickfine AutoProtect Pen Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: January 20, 2012
Received: January 23, 2012

Dear Mr. Sauter:

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.

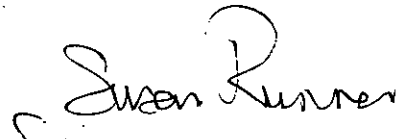
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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



for Anthony D. Watson, B.S., M.S., M.B.A.
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):

Device Name: Clickfine AutoProtect Pen Needle

Indications For Use: The Clickfine AutoProtect pen needle is intended for the hypodermic injection of fluids into the body when attached to an injection pen.

Additionally, after withdrawal of the pen needle from the body, the attached needle safety shield will automatically cover the needle to minimize the risk of accidental needlestick.

Prescription Use __X__ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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