



Food and Drug Administration
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September 12, 2014

Scandinavian Health Limited
c/o Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K141384

Trade/Device Name: WhisperJECT Autoinjector
Regulation Number: 21 CFR 880.6920
Regulation Name: Introducer, Syringe needle
Regulatory Class: II
Product Code: KZH
Dated: August 28, 2014
Received: August 29, 2014

Dear Mr. Job

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 contact the Division of Industry and Consumer Education 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>. 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 Industry and Consumer Education 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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K141384

Device Name

WhisperJECT Autoinjector

Indications for Use (Describe)

The WhisperJECT autoinjector is a non-sterile injection device. It is intended to be used with FDA approved drug products with non-viscous (aqueous) liquid formulations, which are presented in a BD 1.0 mL pre-filled glass syringe with staked needles. It is a reusable injection device for the subcutaneous injection of FDA approved drugs.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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5. 510(k) Summary of Safety and Effectiveness (21 CFR 807.92(a))

Date Prepared: April 24, 2014

5.1 Submitted By:

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Manager
Regulatory Affairs

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5.2 Name of Device:

| | |
|----------------------|----------------------------|
| Common Name: | Auto-Injector |
| Regulation Number: | 880.6920 |
| Classification Name: | Syringe Needle Introducers |
| Classification: | Class II |
| Product Code: | KZH |

5.3 Predicate Devices:

Device name: *Lobster Auto-injector*

510(k) number: K124026

Device name: *Autoject 2*

510(k) number: K945660

Device name: *Autoject 2*

510(k) number: K013362

5.4 Substantial Equivalence

The WhisperJECT™ autoinjector has the same intended use and the same principle of operation as the *Lobster auto-injector* from Scandinavian Health Limited and *Autoject 2* from Owen Mumford. In addition, the equivalence is supported by the performance characteristics and materials used.

5.5 Device Description

The WhisperJECT™ autoinjector is a reusable, spring-loaded injection device that is for general use with 1.0 ml pre-filled glass syringes. WhisperJECT™ autoinjector consists of two subassemblies into which the syringe is loaded and connected together to form the delivery system for self-injection.

5.6 Intended Use

The WhisperJECT™ autoinjector is a non-sterile injection device. It is intended to be used with FDA approved drug products with non-viscous (aqueous) liquid formulations, which are presented in a BD 1.0 mL pre-filled glass syringe with staked needles. It is a reusable injection device for the subcutaneous injection of FDA approved drugs.

5.7 Technological Characteristics

The WhisperJECT™ autoinjector has similar technological characteristics to the Scandinavian Health Limited's *Lobster auto-injector* and Owen Mumford's *Autoject 2*. Differences between the devices do not raise any significant issues of safety and effectiveness.

5.8 Performance Data

WhisperJECT™ autoinjector is being assessed using the applicable sections and methods specified in the ISO standard, ISO 11608:2012, “*Needle-based injection systems for medical use – Requirements and test methods - Part 1: Needle-based injection systems*”. Activation force, needle extension, injection time, completeness of injection, functionality, and robustness will be assessed; WhisperJECT™ auto-injector is intended to meet all requirements and specifications prior to being marketed. As per SHL Pharma's commitment included in section 9.0, WhisperJECT autoinjector device will only be marketed after required testing has been completed and all acceptance criteria met.

5.9 Conclusion

Based on the information presented herein, the WhisperJECT™ autoinjector is substantially equivalent to similar products that have received FDA clearance and are currently legally marketed in the USA.