K124026

SHL GROUP

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

Date Prepared: September 6, 2013

5.1 Submitted By:

Scandinavian Health Ltd.
136, Kuo Sheng 2nd Street
Taoyuan City 330, Taiwan

SEP 13 2013

Contact:
James Haynes
Manager, Regulatory Affairs
SHL Pharma LLC
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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:	*Autoject 2*
510(k) number:	K945660
Device name:	*Autoject 2*
510(k) number:	K013362
Device name:	*Personal Injector™*
510(k) number:	K033696

5.4 Substantial Equivalence

The Lobster Auto-injector has a similar intended use and the same principle of operation as the *Autoject 2* from Owen Mumford and *Personal Injector™* from Union Medico. In addition, the equivalence is supported by the performance characteristics and materials as compared to the *Autoject 2* that was also the predicate devices for *Personal Injector™*. The Lobster Auto-injector shares the same intended use and marketing intent (e.g. prescription and OTC use) as Union Medico's *Personal Injector™*.

5.5 Device Description

The Lobster Auto-injector is a reusable, spring-loaded injection device that is for use with 1.0 ml pre-filled glass syringes with staked needle. Lobster Auto-injector 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

For single patient or individual use only.

The Lobster device is intended for use with a 1mL glass syringe, containing a fixed needle of 27G to 29G gauge, and drug product solutions with a viscosity between 1 and 4 mPa*s. The Lobster auto-injector is a reusable injection device for the subcutaneous injection of FDA approved drugs.

5.7 Technological Characteristics

The Lobster Auto-injector has similar technological characteristics to the Owen Mumford's *Autoject 2*. Differences between the devices do not raise any significant issues of safety and effectiveness.

5.8 Performance Data

Lobster Auto-injector was 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 were assessed; Lobster auto-injector met all

requirements and specifications.

5.9 Conclusion

Based on the information presented herein, the Lobster Auto-injector is substantially equivalent to similar products that have received FDA clearance and are currently legally marketed in the USA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 13, 2013

Scandinavian Health Limited
C/O Mr. James Haynes
Manager, Regulatory Affairs
SHL Pharma LLC
588 Jim Moran Boulevard
DEERFIELD BEACH FL 33442

Re: K124026
Trade/Device Name: Lobster Auto-Injector
Regulation Number: 21 CFR 880.6920
Regulation Name: Syringe Needle Introducer
Regulatory Class: II
Product Code: KZH
Dated: July 25, 2013
Received: July 29, 2013

Dear Mr. Haynes:

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 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. 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,

Mary S. Runner -S

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SHL GROUP

Indications for Use

510(k) Number (if known): *K124026*

Device Name: Lobster Auto-injector

Indications for Use:

The Lobster device is intended for use with a 1mL glass syringe, containing a fixed needle of 27G to 29G gauge, and drug product solutions with a viscosity between 1 and 4 mPa*s. The Lobster auto-injector is a reusable injection device for the subcutaneous injection of FDA approved drugs.

Prescription Use ✔ AND/OR **Over-the-Counter Use** ✔
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C. Chapman
2013.09.13
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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K124026