



Food and Drug Administration
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November 2, 2015

EXELINT International Co.
Mr. Navid Hamid
Senior Regulatory Affairs
2500 Santa Fe Avenue
Redondo Beach, California 90278

Re: K152183

Trade/Device Name: EXELINT SecureTouch Safety Hypodermic Needle

Regulation Number: 21 CFR 880.5570

Regulation Name: Hypodermic Single Lumen Needle

Regulatory Class: II

Product Code: FMI

Dated: August 4, 2015

Received: August 5, 2015

Dear Mr. Hamid:

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" (21 CFR 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,

 Tina
Kiang -S

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)

K152183

Device Name

EXELINT SecureTouch Safety Hypodermic Needle

Indications for Use (Describe)

EXELINT SecureTouch Safety Hypodermic Needle is intended for use with syringes for general purpose aspiration and medication administration. It has an antistick mechanism to cover the needle after use.

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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510(k) Summary

1. Date of Preparation: October 15, 2015
2. Sponsor Identification

EXELINT International, Co.

2500 Santa Fe Avenue
Redondo Beach, CA 90278
Establishment Registration Number: 1035907
Contact Person: Navid Hamid
Position: Manager
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Email: navid@exelmed.com

3. Identification of Proposed Device

Trade Name: EXELINT SecureTouch Safety Hypodermic Needle
Common Name: Safety Hypodermic Needle

Regulatory Information:

Classification Name: Hypodermic single lumen needle
Classification: 2
Product Code: FMI
Regulation Number: 21 CFR [880.5570](#)
Review Panel: General Hospital

Intended Use Statement:

EXELINT SecureTouch Safety Hypodermic Needle is intended for use with syringes for general purpose aspiration and medication administration. It has an antistick mechanism to cover the needle after use.

Device Description:

EXELINT SecureTouch Safety Hypodermic Needle is a sterile, single use, standard luer lock compatible hypodermic needle with a protection shield to enclose the needle after use. The device is available in 18 to 30 gauge in length from 10mm to 50mm. The purpose of this submission is to enable Exelint International, Co. to market a line of safety hypodermic needle.

The proposed device is available in EO sterilized sealed in a sterility maintenance package.

4. Identification of Predicate Device(s)

510(k) Number: K123684
Product Name: Sol-Care Safety Needle

5. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device.

The test results demonstrated that the proposed device complies with the following standards:

- ISO 7864 Third Edition 1993-05-15, Sterile Hypodermic Needles For Single Use.
- ISO 9626 First Edition 1991-09-01, Stainless Steel Needle Tubing For The Manufacture Of Medical Devices [Including: Amendment 1 (2001)]

- ISO 10993-5:2009/(R) 2014, Biological Evaluation Of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity.
- ISO 10993-7:2008(R) 2012, Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals.
- ISO 10993-10:2010, Biological Evaluation of Medical Devices - Part 10: Tests for Irritation And Skin Sensitization.
- ISO 10993-11:2006/(R) 2010, Biological Evaluation Of Medical Devices -- Part 11: Tests For Systemic Toxicity.
- ASTM F756-13, Standard Practice for Assessment of Hemolytic Properties of Materials.
- ASTM F88/F88M-09, Standard Test Method for Seal Strength of Flexible Barrier Materials.
- ASTM F1140/F1140M-13, Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages.
- USP <85> Bacterial Endotoxins Test.
- USP <151> Pyrogen Test.

The performance tests performed on the proposed device are as follows:

- i. Test for Tolerance on Length
- ii. Test for Lubricant
- iii. Test for Bond between Hub and Needle Tube
- iv. Test for Patency Lumen
- v. Dimension Test
- vi. Stiffness Test
- vii. Test for Resistance of Tubing to Breakage
- viii. Test for Resistance to Corrosion
- ix. Testing of Force to Activate the Safety Feature
- x. Testing of Force to Detach the Safety Feature

6. Clinical Test Conclusion
No clinical study is included in this submission.
7. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

Item	Proposed Devices	Predicate Devices
Product Code	FMI	FMI
Regulation Number	21 CFR 880.5570	21 CFR 880.5570
Class	2	2
Intended Use	EXELINT SecureTouch Safety Hypodermic Needle is intended for use with syringes for general purpose aspiration and medication administration. It has an antistick mechanism to cover the needle after use. The safety mechanism covers the needle after use. In the activated position, the needle cover guards against accidental needle stick during normal handling and disposal of the used needle/syringe combination.	The Sol-Care Safety Hypodermic Needle is used in conjunction with a standard syringe. This device is used for aspiration and administration of medication. The Sol-Care Safety Hypodermic Needle safety mechanism covers the needle after use. In the activated position, the needle cover guards against accidental needle stick during normal handling and disposal of the used needle/syringe combination.

Configuration	Hub, Needle Cannula, Needle Cap, Protection Shield	Hub, Needle Cannula, Needle Cap, Protection Shield
Force to activate the safety feature	$\leq 4\text{N}$	30G~28G<4N; 27G~21G<5.5N; 20G~18G<7.5N
Force to detach the safety feature	$\geq 30\text{N}$	$\geq 30\text{N}$
Operation Mode	Manual	Manual
Single Use	Yes	Yes
Needle Gauge	18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G	18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G
Performance specification	Comply with ISO 7864, ISO 9626	Comply with ISO 7864, ISO 9626
Material	Needle cannula: Stainless Steel	Needle cannula: Stainless Steel
	Needle hub and protection shield: Polypropylene	Needle hub and protection shield: Polypropylene
	Needle cap: Polypropylene	Needle cap: Polypropylene
Biocompatibility	Conforms to ISO 10993 Tests: Cytotoxicity, Skin Sensitization, Intracutaneous Irritation, Systemic Toxicity, In Vitro Hemolysis, Pyrogen	Conforms to ISO 10993

8. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed device is determined to be Substantially Equivalent (SE) to the predicate device.