



Food and Drug Administration
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February 10, 2016

Artsana S.p.A
c/o Mr. H. Carl Jenkins
Official Correspondent
The Wood Burditt Group, LLC
10 E. Scranton Ave., Ste. 201
Lake Bluff, Illinois 60044

Re: K151311
Trade/Device Name: Safe Block Pen Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: January 7, 2016
Received: January 11, 2016

Dear Mr. Jenkins:

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)

K151311

Device Name

Safe Block Pen Needle

Indications for Use (Describe)

Safe Block Pen Needle is intended for use with pen injector devices for the injection of fluids, including insulin. Additionally, the attached safety shield automatically locks in place and reduces the occurrence of accidental sticks from the patient end of the needle.

The shield also serves to conceal the needle before and after injection.

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

K151311

Date prepared: May 12, 2015

Submitter / Contact Person	H. Carl Jenkins The Wood Burditt Group 10 E. Scranton Ave, Suite 201 Lake Bluff, IL 60044 (ph) 847-234-7500 x 205 (fax) 847-578-0728 (email) hcjenkins@woodburditt.com
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Applicant	Artsana S.p.A Via Saldarini Catelli 1, 22070 Grandate COMO – ITALY Registration Number: 9612764
Manufacturer	Artsana S.p.A Unit Production N°30, Via Saldarini catelli 6/10, 22070 Grandate COMO - ITALY

Device Name

Trade Name	Safe Block Pen Needle
Proprietary Name	Safe Block Pen Needle G31x5mm Safe Block Pen Needle G31x8mm
Common Name	Sterile Disposable Safety Pen Needle
Classification Name	Hypodermic Single Lumen Needle
Classification Panel	80 – General Hospital
Regulation	21 CFR 880.5570
Product Code	FMI
Classification	II



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Reason for 510(k) Submission

The applicant device is a new device.

Device Description

SAFETY PEN NEEDLE. Safe Block Pen Needle is designated for use with pen injector for subcutaneous injection of a desired dose of drugs approved for delivery using a pen needle. Safe Block Pen Needle are offered in one gauge size (31G) and in a various lengths (5mm and 8mm). The Safe Block Pen Needle is sterile (ETO sterilization), non toxic and non-pyrogenic. It's a disposable single use device.

Additionally the Safe Block Pen Needle is designed to reduce occurrence of accidental needle sticks from patient end of the needle by providing a shield that covers and locks the needle after use. Prior to injection the user will attach the Safe Block Pen Needle to the pen. The shield of Safe Block Pen Needle will hide the needle from the user prior to use. As the user proceeds with inserting the needle into the skin the shield will retract. After the injection is completed and needle is removed from the skin, the shield will automatically extend to cover the needle and lock in place. The Safe Block Pen Needle should be removed from the pen and discarded.

Indications for Use:

Safe Block Pen Needle is intended for use with pen injector devices for the injection of fluids, including insulin. Additionally, the attached safety shield automatically locks in place and reduces the occurrence of accidental sticks from the patient end of the needle. The shield also serves to conceal the needle before and after injection.

Predicate Device Summary Table

Based on the comparison of the device features, materials, intended use and performance the Safe Block Pen Needle was shown to be substantially equivalent to the commercially available predicate devices indicated in the table below.

Product	Applicant	510(k) #	Clearance Date
Artsana Hypodermic needles, Artsana Insupen insulin pen needle	Artsana S.p.A.	K051783	2005.10.04
Novo Fine Auto Cover	Novo Nordisk Inc	K050106	2005.03.30



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Technological characteristics and comparison

Artsana Safe Block 31Gx5 mm and 31Gx8 mm is substantially equivalent to the Novo Nordisk – Novo Fine Autocover (K050106) and the Artsana pen needles (K051783). They are all class II devices and, as explained below, the intended use is the same for all the three products. They are all designed for single use in conjunction with pen injection for subcutaneous administration of drugs approved for delivery using a pen needle, both in hospital and domestic environment. Furthermore, both NovoFine Autocover and Safe Block have safety features to prevent people from needlestick injuries. For what is concerned to the injection, the working principle is the same for all the three devices: before the injection, the protective seal is removed from the plastic primary container. Then, keeping the needle in the container, the threaded hub is screwed on the injection device (as explained in the Safe Block directions for use) and the injection is prepared according to the pen injector directions for use. After the primary container is removed, both Safe Block and Autocover have a further needle shield, that is not removable, hiding the cannula before and after the injection (this is an important feature for people that are afraid of needles).

The needle cover is pushed on the skin, retracting into the product: in this way, the cannula penetrates into the patient’s skin and the drug can be delivered. Then, when the cannula is removed from the skin, the shield automatically covers the cannula again: now the shield is permanently locked, protecting the needle tip and both preventing from the pen needle reuse and reducing the risk of accidental injuries. Finally, the needle is removed from the injection device and disposed as per local safety practices and regulations on sharp devices.

Predicate device Autocover and applicant device Safe Block have the same working principle of the safety mechanism and they’re very similar also in terms of product dimensions and shape.

Product Dimensions	Colour of the hub	Colour of the primary container (cover)	Configuration of the tip
G31x5mm	Purple	White	Per ISO 11608-2, section 4.5, visually sharp at 2.5X magnification, designed to minimize coring and fragmentation
G31x8mm	Light blue	White	Per ISO 11608-2, section 4.5, visually sharp at 2.5X magnification, designed to minimize coring and fragmentation



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Component materials are presented in the table below:

Component	Applicant Device Material	Predicate Device Material (K051783)
External cover	PP (non toxic, medical grade)	Identical
Needle hub	PP (non toxic, medical grade)	Identical
Ring	HDPE (non toxic, medical grade)	Identical
Shield	HDPE (non toxic, medical grade)	Identical
Primary Container	HDPE (non toxic, medical grade)	Identical
Seal	Medical Paper	Identical
Cannula	Stainless Steel	Identical
Glue	UV acrylate	Identical
Lubricant	Silicone oil mixture (non toxic, medical grade) composed by 3 different elements (Dispersion fluid, Medical Silicone, Solvent)	Identical
Spring	Stainless Steel	N/A
Colorants	Pigments for polymer	Identical

Clinical test:

No clinical tests were conducted in support of this 510(k) submission.

Non Clinical Tests performed:

Testing demonstrated the safety feature performance through laboratory testing and simulated user studies.

Bench testing related to performance, safety, effectiveness and specifications of the proposed device was also conducted in order to verify the equivalence of performances with the predicate devices.



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Table of specifications (including relevant tests) for applicant and predicate devices, below:

Feature / Characteristics	Applicant Device	Predicate K051783 (ARTSANA PEN NEEDLES, ARTSANA INJECTION NEEDLES)	Predicate K050106 (NOVOFINE AUTOCOVER 30G x 8mm)
Intended Use	It is intended for use with pen injector devices for the injection of drugs, including insulin. Additionally the attached safety shield automatically locks in place and reduces the occurrence of accidental sticks from the patient end of the needle. The shield also serves to hide the needle before and after injection	Insulin delivery	For use in conjunction with insulin injection delivery devices for subcutaneous administration of sterile parenteral insulin products.
Length / Tolerance	5 mm, 8 mm (tolerance as per ISO 11608-2)	6 mm, 8 mm, 12 mm (tolerance as per ISO 11608-2)	8 mm (tolerance as per ISO 11608-2)
Gauge	G31 (as per ISO 9626)	G31, G29 (as per ISO 9626)	G30 (as per ISO 9626)
Tip configuration	Per ISO 11608-2, section 4.5, visually sharp at 2.5X magnification, designed to minimize coring and fragmentation	Per ISO 11608-2, section 4.5, visually sharp at 2.5X magnification, designed to minimize coring and fragmentation	Per ISO 11608-2, section 4.5, visually sharp at 2.5X magnification, designed to minimize coring and fragmentation
Cover colour	White	White	Transparent / White
Hub/needle bond strength	Per ISO 11608-2	Per ISO 11608-2	-
Biocompatibility	As per ISO 10993-1	As per ISO 10993-1	-
Compatibility test	ISO 11608-2 (torque)	ISO 11608-2 (torque)	-



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(type A needles)	test)	test)	
Lubrication	As per ISO 11608-2	ISO 11608-2	-
Safety mechanism Activation	As per ISO 23908, internal protocol and test results	-	As per ISO 23908, internal protocol and test results
Safety overriding/unlocking force after activation	As per ISO 23908, internal protocol and test results	-	As per ISO 23908, internal protocol and test results

Sterilization:

Product is EO sterilized in house by manufacturer. Sterilization process is validated using current standard ISO 11135-1:2007.

The method used to validate the sterilization cycle is HSKP method (ISO 11138-1:2006)

The shelf life of the product, considering the integrity of the packaging and the sterility and physical properties, is 5 years from the production date. The expiring date and sterilization methods are clearly indicated on the pack. The product shelf life is ensured if the product is stored and transported in compliance with the environmental condition stated on the pack and on the external carton.

Biocompatibility:

The product has successfully undergone the biocompatibility evaluation required by ISO 10993-1 for:

- Cytotoxicity (ISO 10993-5) ,
- Emocompatibility (ISO 10993-4, ASTM F756),
- Sensitization and skin reactivity (ISO 10993-10),
- Acute systemic toxicity (ISO 10993-11).

Conclusion

The applicant device is substantially equivalent in its intended use, technology / principal of operation, materials, and performance to the predicate devices identified in this 510(k) submission.