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510(k) Summary

This 510(k) was prepared in April 2013

1. Name and address of the 510(k) Owner

Company: B. Braun Melsungen AG, Division Hospital Care
Name: Dr. Stefan Seidel
Position: Head of Regulatory Affairs Non-active Medical-Devices CoE IV-Systems
Address Carl-Braun-Strasse 1
34212 Melsungen
Germany
Phone: +49 5661 71-2608
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Email: stefan.seidel@bbraun.com
Establishment registration number: 9610825

2. Name and classification of the device

Name:	ExtaviPro™ Sterican™ 30G
Common name:	Hypodermic single lumen needle
Classification	Class II, Hypodermic single lumen needle, 21 CFR 880.5570, Product Code FMI

3. Predicate device

This applications claims substantial equivalence to the following predicate device:

Name:	Sterican™ Needles
Common name:	Hypodermic single lumen needle
Classification:	Class II, Hypodermic single lumen needle, 21 CFR 880.5570,
Product Code:	FMI
510(k)-number:	K072247

4. Description of the device

ExtaviPro™ Sterican™ 30G hypodermic needles are comprised of a steel cannula that is sharpened to a point at one end. The other end is bonded to a yellow color-coded female Luer Lock hub designed for attachment to a corresponding male connector, such as a syringe. A protective cap must be removed before injection.

4.1. Intended Use

ExtaviPro™ Sterican™ 30G Hypodermic needles, when attached to a male connector, are intended to be used to inject fluid into, or withdraw fluids from, parts of the body below the surface of the skin.

4.2. Technological Characteristics

ExtaviPro™ Sterican™ 30G hypodermic needles are substantially equivalent to the predicate Sterican™ hypodermic needles. They are produced from the same materials, using the same equipment at the same manufacturing site. The sterilization process is the same and has been validated according to the same procedures. Primary packaging that assures sterility and shelf life is the same.

ExtaviPro™ Sterican™ 30G is sterile and pyrogen-free.
ExtaviPro™ Sterican™ 30G consists of the following materials:

- Needle tube — AISI SUS 304 stainless steel
- Needle hub — Polypropylene with masterbatch colorant (yellow)
- Needle adhesive — UV curing adhesive
- Needle lubricant — Silicone oil
- Needle cover — High Density Polyethylene (HDPE)

There are two differences between ExtaviPro™ Sterican™ 30G and Sterican™ hypodermic needles:

- The device is a 30G needle and is thus smaller than all other Sterican™ needles marketed so far under K072247. There are, however, quite a number of 30 G hypodermic needles already on the US market, as for instance covered by K113186 (Novotwist needle, Novo Nordisk).
- ExtaviPro™ Sterican™ 30G will exclusively be sold to Novartis. As customer requirement, a small collar is around the needle hub. This does not change the performance of the device because the inner surface geometry was not changed.

5. Tests

5.1. Non-clinical tests

Functional testing was performed to demonstrate safety and effectiveness and to ensure that the ExtaviPro™ Sterican™ 30G needles meet the requirements of the standards

- ISO 7864:1993(E), Sterile hypodermic needles for singe use
- ISO 9626:1991/Amd. 1:2001(E), Stainless steel needle tubing for the manufacture of medical devices
- ISO 594-1, Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment-Part 1: General requirements
- ISO 594-2, Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment-Part 2: Lock fittings.

Some of the tests have been executed on samples before EtO-Sterilization and after 3 sterilization cycles as well as after accelerated ageing, to demonstrate a shelf life of at least one year.
The needles passed these tests and thus showed that they are as safe as the predicate needles.

5.2. Clinical tests

Not applicable

5.3. Conclusion

ExtaviPro™ Sterican™ 30G needles passed the tests. Since materials, manufacturing and sterilization processes are the same as for the predicate device, no new questions arise from this side. It is therefore concluded that ExtaviPro™ Sterican™ 30G needles are as safe, as effective, and perform as well as the predicate device.

6. Other information

Not applicable

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

July 15, 2013

B. Braun Melsungen AG
C/O Dr. Stefan Seidel
Head of Regulatory Affairs
Yes Medical Device Services GmbH
Bahnstrasse 42-46
Friedrichsdorf, Hesse
GERMANY 61381

Re: K131040
Trade/Device Name: ExtaviPro™ Sterican™ 30G
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: April 10, 2013
Received: April 22, 2013

Dear Dr. Seidel:

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,

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

Indications for Use

510(k) number (if known): K131040

Device Name: ExtaviPro™ Sterican™ 30G

Indications for Use:

ExtaviPro™ Sterican™ 30G Hypodermic needles, when attached to a male connector, are intended to be used to inject fluid into, or withdraw fluids from, parts of the body below the surface of the skin.

Prescription Use _____X___ AND/OR Over-The-Counter Use _____
(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)

Mary S. Runner -S
Susan Runner DDS M 2013.07.15
11:20:52 -04'00'

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

510(k) Number: K131040