December 18, 2017

Ferrosan Medical Devices SP. Z O.O.
% Paul Dryden
Consultant
ProMedic, LLC
24301 Woodsage Dr.
Bonita Springs, Florida 34134-2958

Re: K171193
Trade/Device Name: Certa Catheter Continuous Peripheral Nerve Block Catheter Set
Regulation Number: 21 CFR 868.5120
Regulation Name: Anesthesia Conduction Catheter
Regulatory Class: Class II
Product Code: BSO
Dated: November 15, 2017
Received: November 16, 2017

Dear Paul Dryden:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Tara A. Ryan -S
2017.12.18 06:04:25 -05'00'

for
Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*

**K171193**

Device Name

**Certa Catheter Continuous Peripheral Nerve Block Catheter Set**

Indications for Use *(Describe)*

Certa Catheter™ continuous peripheral nerve block catheter set is indicated for delivery of medication for regional anesthesia and pain management in lower extremity blocks. It may be used by a qualified healthcare professional in a perioperative monitored care setting.

Certa Catheter™ is intended for use in adult patients only. It should always be inserted and placed under ultrasound guidance by a healthcare professional.

The Certa Catheter has not been evaluated for use in upper extremity blocks.

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

**XX** 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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Ferrosan
Medical Devices

# 510(k) Summary
# Certa Catheter
# December 15, 2017

| | |
|---|---|
| **Official Contact:** | Elzbieta Porebska-Guillemant, QA Manager |
| **Proprietary or Trade Name:** | Certa Catheter ™ Continuous Peripheral Nerve Block Catheter Set |
| **Common/Usual Name:** | Catheter, Anesthetic |
| **Classification Name:** | BSO, Anesthesia conduction catheter, CFR Title 21, 868.5120, Class II |
| **Predicate Device:** | K143164 – Halyard ON-Q QuikBloc Over-the-Needle Catheter set |

**Device Description:**

Certa Catheter™ is a single patient use, disposable device which is the combination of a needle and catheter, intended for delivery of local anesthetic for continuous peripheral nerve blocks.
Certa Catheter™ is intended to be placed with the use of ultrasound guidance. The procedure is performed using aseptic technique.

Certa Catheter™ consists of a curved needle to which the catheter is attached. The curved needle is available in several radius and lengths. To assist with the control of the needle during insertion, there is a Hub which allows the user to rotate the needle during the insertion and placement along or above the target nerve. The Hub is removed and then the user is able to grab the needle tip and pull the catheter through the entry and exit locations. The needle is then cut from the catheter and the user is able to pull the catheter back and forth to locate the eyelets in the proper location along or above the target nerve. The catheter is then fixed on one side to secure its location. The system consists of: Curved needle; Hub – a handle that helps during insertion and is removed afterwards; which has a Luer port; Catheter with single or multiple orifices; and echogenic markings for ultrasound detection.

**Indications for Use**

Certa Catheter™ continuous peripheral nerve block catheter set is indicated for delivery of medication for regional anesthesia and pain management in lower extremity blocks. It may be used by a qualified healthcare professional in a perioperative monitored care setting.

Certa Catheter™ is intended for use in adult patients only. It should always be inserted and placed under ultrasound guidance by a healthcare professional.

The Certa Catheter has not been evaluated for use in upper extremity blocks.

**Contraindications and Lessons Learned**

Certa Catheter™ is contraindicated for all

- intraneural
- intravascular
- intrapleural
- epidural
- intrathecal placement
- Always use Certa Catheter™ under ultrasound guidance.
- Do not use Certa Catheter™ in patients with coagulopathies.
- Do not use Certa Catheter™ in patients with pre-existing neurological diseases.
- Do not use Certa Catheter™ in patients with severe hepatic and/or renal insufficiency where the clearance of local anesthetic may be delayed. Please refer to the Prescribing Information for the local anesthetic used.
- Do not use Certa Catheter™ in patients at risk of developing acute compartment syndrome as local anesthetic may mask the hallmark sign of acute compartment syndrome.
- Do not use Certa Catheter™ with local anesthetic if the patient is allergic to local anesthetic. Always consult the Prescribing Information for the local anesthetic used.
- Do not use Certa Catheter™ in patients with infection or inflammation at the insertion and/or exit sites.
- Do not use Certa Catheter™ in patients with known allergies to one or more of the materials used.

ul. Koksowa 3, 70-031 Szczecin, Poland
tel. +48 91 4283 400, fax +48 91 4283 315
info@ferrosanmd.com www.ferrosanmd.com
NIP: 955-233-11-59 REGON: 321192063

| |
|---|
| - Before placing a continuous peripheral nerve block always assess the patient for any risk factors that may contribute to perioperative nerve injury including patient risk factors (e.g. pre-existing neurologic disorders, pre-existing diabetes or extremes of body habitus). This may also include if patient has excessive anxiety that may lead to inability to respond to interventions and inability to tolerate positioning.<br>- Place the catheter above or along the nerve to reduce the risk of transient neurologic deficits.<br>- It is recommended to use single hard fixation to avoid discomfort and transient neurologic deficits. |
| **Environments of Use and Patient Population** |
| The environment of use is hospital, sub-acute and clinic settings. For use with adults. |

| **Predicate Device Comparison** | | |
|---|---|---|
| **Features** | **Predicate**<br>**Halyard, On-Q (K143164)** | **Proposed**<br>**Certa** |
| **Indications for use** | The On-Q* QuikBloc* Over-the-Needle Catheter set is indicated for delivery of medication for regional anesthesia and pain management. Route of administration may be intraoperative, percutaneous, or perineural | Certa Catheter™ continuous peripheral nerve block catheter set is indicated for delivery of medication for regional anesthesia and pain management in lower extremity blocks. It may be used by a qualified healthcare professional in a perioperative monitored care setting.<br><br>Certa Catheter™ is intended for use in adult patients only. It should always be inserted and placed under ultrasound guidance by a healthcare professional.<br><br>The Certa Catheter has not been evaluated for use in upper extremity blocks. |
| **Environment of Use** | Hospital, sub-acute and clinic settings | Hospital, sub-acute and clinic settings |
| Patient Population | Patients for regional analgesia and anesthesia | Adult patients for regional analgesia and anesthesia |
| **Contraindications** | Not indicated for epidural or intravascular delivery | Not indicated for epidural or intravascular delivery.<br><br>Moreover, not indicated for intraneural, intrapleural or intrathecal.<br><br>To be placed along or above target nerve.<br><br>Use a single hard fixation of one catheter end |
| **Principle of Operation** | Insertion of a catheter near the nerve site and infusion of drug | Insertion of a catheter near the nerve site and infusion of drug |
| **Technique of Catheter Placement** | Over the needle catheter insertion | Through to through needle is attached to catheter and upon exit of needle the catheter is then pull through |
| **Echogenic properties for ultrasound guidance** | Yes<br>On needle | Yes<br>On the catheter |
| **Insertion method** | Over-the-needle<br>Catheter is fitted over the needle then needle inserted | Catheter is attached to end of needle |
| **Sizes of catheter** | **Inner diameter:ø1mm (measured)**<br>**Outer diameter: ø1,6mm (measured)** | Inner diameter:ø0,6mm on nominal<br>Outer diameter: ø1,2mm on nominal |

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| Features | Predicate<br>Halyard, On-Q (K143164) | Proposed<br>Certa |
|---|---|---|
| **Length of catheter** | Full length:76mm (from product description)<br>Length to first dosing hole: 71mm (measured) | Full length: 600mm on nominal<br>Length to first dosing hole: 400mm on nominal |
| **Number of holes** | 3 side holes and 1 front hole | 1 hole variant: 1 thru hole, so 2 side holes<br>3 holes variant: 3 thru holes, so 6 side holes |
| **Needle configurations** | Straight of different lengths and gauges | Curvature Radius – 50, 75, 120 mm<br>Length – 100 and 160 mm<br>Gauge - 19 |
| **Components of Catheter Set** | Multiple needle sizes and length<br>Catheter<br>Extension set for needle<br>Extension set for catheter | Multiple needle sizes and length<br>Catheter |
| **Maximum time left in place** | < 30 days | < 30 days |
| **Disposable** | Single patient, disposable | Single patient, disposable |
| **Sterile** | Yes | Yes |
| **Shelf-life** | Greater than 1 year | 3 years |
| **Biocompatibility**<br>**ISO 10993-1** | ISO 10993-1 considers the components as:<br>Externally communicating, Tissue/bone, Limited and Prolonged duration of use<br>and<br>Surface Contact, Intact Skin and Breached or comprised surfaces, Limited and Prolonged duration of use. | ISO 10993-1 considers the components as:<br>Externally communicating, Tissue/bone, Limited and Prolonged duration of use<br>and<br>Surface Contact, Intact Skin and Breached or comprised surfaces, Limited and Prolonged duration of use. |
| **Performance Testing – Non-clinical** | | |
| **Shelf-life** | | |
| **Strength of bond** | Average bond strength between catheter and its luer is 34.64N +/- 2.34N | Average bond strength between catheter and its luer is 34.91N +/- 4.09 |
| **Tensile strength** | Tested and compared to subject device the average tensile strength of catheter (at its weakest point) is 30.28N +/- 1.66N | Tested and compared to predicate the average tensile strength of catheter (at its weakest point) is 20.12N +/- 0.75N<br><br>3 holes model Average tensile strength of catheter (at its weakest point) is 18.43N +/- 0,33N |
| **Leakage** | Tested to EN 1618:1997 Annex B | Tested to EN 1618:1997 Annex B |
| **Luer fitting** | Compliant with ISO 594-2 | Tested and compliant with ISO 594-2 |
| **Sharpness** | Average penetration force is 3.7N +/- 0.31N | Average penetration force is 2.93N +/- 0.33N |
| **Flow rate** | Average flow rate is 83.91ml/min +/- 2.73ml/mi | Average flow rate 5.24ml/min +/-0.08ml/min<br><br>3 holes model average flow rate 5.2ml/min +/- 0.1ml/min |
| **Catheter Kinking** | Reported kink resistant up to 0.25” (6.35mm) catheter radius | Kink resistant up to at least 1.11mm catheter radius |

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**Discussion of substantial equivalence**

The Certa Catheter™ is viewed as substantially equivalent to the predicate device because:

**Indications for Use –** The proposed indications for use are similar that is for delivery of medication for regional anesthesia and pain management. Route of administration is in a perioperative monitored care setting.
**Discussion -** The Certa Catheter is limited to lower extremity blocks which are a subset of the predicate.

**Patient Population –** The patient population is adults.
**Discussion -** There are no differences in the patient population.

**Environment of Use –** The proposed environments of use are the same.
**Discussion –** There are no differences in the environments of use.

**Technology** – The technology for insertion with a needle and inserting a catheter with holes of infusion of the medication is similar. The use of echogenic markings to assist with visualization under ultrasound guidance is also similar.
**Discussion of Differences –** The technology of using a curved needle to insert the catheter via a through to through technique vs. over the needle catheter insertion and placement technique allows the clinician to be able to move the catheter and the drug orifices to the desired location by pulling the catheter from either end whereas the over the needle technique does not allow one to adjust the catheter drug orifice as easily. In the end the insertion technique and catheter placement was shown in the clinical studies to be substantially equivalent for blocks in lower extremities. In addition, comparative performance testing demonstrated that the specifications of the needle and catheter were substantially equivalent to the predicate or reference device.

**Differences –** The difference is the catheter insertion and placement technique and the design of the device involves both the use of needle inserted near the nerve and then the placement of a catheter. Having a curved needle, the catheter attached to the needle, single or multiple orifices in the catheter, physical specifications, and method of catheter fixation do not raise new or different safety or effective concerns.

**Performance Testing – Non-clinical**

**Biocompatibility and Materials –** The materials have been evaluated per ISO 10993-1. They are characterized as:

- External Communicating, Tissue / Bone / Dentin communicating
- Surface Contact, Intact Skin and Breached
- Duration of Use – Limited and Prolonged (> 24 hours < 30 days)

**Discussion -** We tested the all applicable components according to ISO 10993-1 and the results supported the materials as meeting the biocompatibility requirements.
**Differences –** Any differences in materials were evaluated with the testing which demonstrated that the proposed meets the ISO 10993 requirements and the proposed materials have not raised different questions of safety and effectiveness.

**Sterility** – We performed sterilization via EO validation. EO and ECH residuals were evaluated per ISO 10093-7 and LAL endotoxins. The sterilization was validated.

**Effects of Aging –** We performed testing related to aging to evaluate the performance of the device post-aging. The results supported that aging does not have an effect on the performance of the subject device.

**Comparative Performance -** Comparative bench testing was performed to demonstrate that the subject device performed substantially equivalent to the predicate. The tests included:

- Strength of bonds
- Tensile strength
- Leakage
- Luer fitting
- Sharpness
- Flow rate
- Catheter Kinking

**Discussion –** There were some differences in the comparative performance.

- Tensile strength while lower when compared to the predicate comparison to a legally marketed reference device demonstrated that the subject device had higher tensile when compared to the reference device which had the similar indications for use. The results demonstrated that the tensile strength of the various bonds and connections were within the specifications of the predicate and reference devices which have been found to be safe and effective for the similar indications. The differences do not raise different concerns of safety and effectiveness.
- Flow rate is lower than the predicate but the clinician determines the effectiveness of a block after injection of the anesthetics and the subject does allows for a slower flow rate and allows the clinician time to assess the level of block vs. a higher flow rate device. The quality of a nerve block is a clinical decision under the control of the clinician. This lower flow rate does not alter the risk of safety profile.
- There were no significant differences between the subject device and the predicate which would raise different concerns of safety and effectiveness.

**Clinical Study Summary** - We provided the results of several clinical trials related to the insertion technique of the Certa Catheter™. The studies included healthy volunteers where the insertion technique of the Certa Catheter was part of the studies. In addition, a review of the catheter fixation method and any infection at the needle puncture sites were noted. No adverse events were recorded on study days in the two studies.

In addition, a review of the Safety and Risk Profile for peripheral nerve block catheters included MAUDE Database search, Literature Search for Nerve damage and Infection supported that the Certa Catheter™ and the predicate had substantially equivalent safety and risk profiles.

One of the studies performed on healthy individuals with a high level of mobility showed an increased incidence of transient neurologic deficits when the catheter was placed below the nerve [*CONTINUOUS ADDUCTOR CANAL BLOCK WITH A SUTURE-METHOD CATHETER – PRIMARY PLACEMENT AND SECONDARY REPOSITIONING*; ESRA Academy. Lyngeraa T. Sep 8, 2016; 138581]

**Discussion -** As a result of the Lyngeraa study, it is recommended that the catheter is placed above or along the nerve (not below or circumferentially around the nerve), with fixation on one side not two, to reduce the risk of nerve injury.

The studies that used this insertion technique support the safety and substantial equivalence of the Certa Catheter.

**Substantial Equivalence Conclusion**

Based upon the comparison of the indications for use, patient population, environment of use, technology or principle of operation, and performance the subject device can be found substantially equivalent to the predicate.