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

January 22, 2016

Solo-Dex, Inc.
% Albert Rego, Ph.D.
Regulatory Consultant
Albert Rego, Ph.D., Inc.
27001 La Paz Road, Suite 312
Mission Viejo, California 92691

Re: K151072
Trade/Device Name: Solo-Dex Fascile® Continuous Peripheral Nerve Block Catheter and Needle Kit
Regulation Number: 21 CFR 868.5150
Regulation Name: Anesthesia Conduction Needle
Regulatory Class: Class II
Product Code: BSP
Dated: December 22, 2015
Received: December 24, 2015

Dear Dr. Albert Rego:

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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151072

Device Name
Solo-Dex Fascile® Continuous Peripheral Nerve Block Catheter and Needle Kit

Indications for Use *(Describe)*
The Solo-Dex Fascile® Continuous Peripheral Nerve Block Catheter and Needle Kit is intended for use in regional anesthesia and pain therapy to locate peripheral nerves by transferring electrical impulses from a nerve stimulator, or to be seen by ultrasound visualization of the device. The needle is used to inject and facilitate the continuous and/or intermittent administration of local anesthetics or analgesics to the targeted nerve bundle in surgical procedures.

In packaged set configurations, the Solo-Dex Fascile® Continuous Peripheral Nerve Block Catheter and Needle Kit, consisting of the peripheral nerve block needle, catheter, and related peripheral nerve block procedural accessories, is intended to provide continuous and/or intermittent infusion of local anesthetics and analgesics for peripheral plexus anesthesia and pain management during pre-operative, peri-operative and post-operative periods associated with surgical procedures. The catheter may remain indwelling for up to 72 hours.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
(As required by 21 CFR 807.92)

I. SUBMITTER:	Solo-Dex, Inc. 3 Moonlight Isle Ladera Ranch, CA 92694 USA
Contact Person:	Albert Rego Ph.D., Inc. 27001 La Paz Road, Suite 312 Mission Viejo, CA 92691 Contact: Albert Rego Phone: (949) 770-8710
Date Prepared:	January 20, 2016
II. DEVICE:	
Trade Name:	Solo-Dex Fascile® Continuous Peripheral Nerve Block Catheter and Needle Kit
Common Name:	Anesthesia Conduction Needle [Peripheral Nerve Block Needle, Anesthetic Conduction Needles, W/Wo introducer (21 CFR 868.5150)]
Classification Panel:	Anesthesiology
Regulatory Class:	Class II
Product Code:	BSP
III. PREDICATE DEVICE:	Complex® C Continuous Peripheral Nerve Block Needle (K121846)

IV. DEVICE DESCRIPTION:

Solo-Dex Fascile® Continuous Peripheral Nerve Block Catheter and Needle Kit is a needle comprised of an open tip catheter over a needle. The Fascile kit is comprised of different key components required to complete the Peripheral Nerve Block procedure.

V. INDICATIONS FOR USE:

The Solo-Dex Fascile® Continuous Peripheral Nerve Block Needle is intended for use in regional anesthesia and pain therapy to locate peripheral nerves by transferring electrical impulses from a nerve stimulator, or to be seen by ultrasound visualization of the device. The needle is used to inject and facilitate the continuous and/or intermittent administration of local anesthetics or analgesics to the targeted nerve bundle in surgical procedures.

In packaged set configurations, the Solo-Dex Fascile® Continuous Peripheral Nerve Block Set, consisting of the peripheral nerve block needle, catheter, and related peripheral nerve block procedural accessories, is intended to provide continuous and/or intermittent infusion of local anesthetics and analgesics for peripheral plexus anesthesia and pain management during pre-operative, peri-operative and post-operative periods associated with surgical procedures. The catheter may remain indwelling for up to 72 hours.

VI. TECHNOLOGICAL CHARACTERISTICS:

Solo-Dex Fascile® Continuous Peripheral Nerve Block Needle has the same fundamental scientific technology as the Complex® C Continuous Peripheral Nerve Block Needle (K121846).

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The comparison of features and operation principles between Solo-Dex Fascile® Continuous Peripheral Nerve Block Needle from Solo-Dex, Inc., and Complex® C Continuous Peripheral Nerve Block Needle (K121846) from B. Braun Medical, Inc. is listed as follows:

Parameter	Solo-Dex Fascile® Continuous Peripheral Nerve Block Catheter and Needle Kit 510(k) - (K151072)	Complex® C Continuous Peripheral Nerve Block Needle 510(k) (K121846), B. Braun Medical, Inc.	Comparison Substantially Equivalent or Equivalent
Common Name	Peripheral Nerve Block Needle, Anesthetic Conduction Needles, W/Wo introducer (21 CFR 868.5150)	Peripheral Nerve Block Needle, Anesthetic Conduction Needles, W/Wo introducer (21 CFR 868.5150)	Substantially Equivalent
General Characteristics			
Description	Solo-Dex Fascile Continuous Peripheral Nerve Block Catheter and Needle Kit is a needle comprised of an open tip catheter over a needle. The Fascile kit is comprised of different key components required to complete the Peripheral Nerve Block procedure. The description of key components are as follows:	The Contiplex® C Continuous Peripheral Nerve Block Needle is a needle comprised of an open tip catheter over an insulated needle with a positioning component, a needle hub with integrated injection tubing and cable, and connection tubing. The key components in B. Braun system are as follows:	Substantially Equivalent
	1. Catheter and Needle Combination: The needle provides the clinician with the ability of placing the catheter / needle combination at the regional block site. Upon placement, the needle is withdrawn leaving the catheter intact and available for infusion when connected to a syringe or infusion pump.	1. Catheter and Needle Combination: The combination is used for placing the needle and catheter at the regional block site. After placement at the site, the needle is withdrawn with the catheter remaining at the site. The catheter may be attached to a syringe or infusion pump.	Substantially Equivalent
	2. Stimulating Cable: Fascile kit includes a stimulating cable that when connected to the needle provides electrical stimulation to the targeted nerve bundle if required	2. Stimulating Cable: The stimulating cable is integrated into the needle. The needle may provide stimulation to the targeted nerve bundle if required.	Substantially Equivalent

Parameter	Solo-Dex Fascile® Continuous Peripheral Nerve Block Catheter and Needle Kit 510(k) - (K151072)	Complex® C Continuous Peripheral Nerve Block Needle 510(k) (K121846), B. Braun Medical, Inc.	Comparison Substantially Equivalent or Equivalent
	3. 0.2µ Filter: A 0.2µ filter is available within the kit and may be used for particle filtration of the anesthetic drug. The kit utilizes the Perifix 0.2µ filter (or equivalent).	3. 0.2µ Filter: The B. Braun Perifix 0.2µ filter is available within the kit and may be used for particle filtration of the anesthetic drug.	Substantially Equivalent
	4. Adhesive strips and transparent occlusive dressing: Adhesive strips and occlusive dressing are available within the kit and may be used for securing the catheter at the insertion site. The adhesive strips and occlusive dressing are off the shelf components.	4. Perifix PinPad Filter Fixation Device: The B. Braun Perifix PinPad is used for securing the Perifix 0.2µ Filter.	Substantially Equivalent (securement devices)
	5. Extension Set: The Extension Set serves as the interface between the needle / catheter and the syringe / infusion pump.	5. Extension Set: Same as Solo-Dex Fascile kit.	Substantially Equivalent
Indications for Use	The Solo-Dex Fascile® Continuous Peripheral Nerve Block Needle is intended for use in regional anesthesia and pain therapy to locate peripheral nerves by transferring electrical impulses from a nerve stimulator, or to be seen by ultrasound visualization of the device. The needle is used to inject and facilitate the continuous and/or intermittent administration of local anesthetics or analgesics to the targeted nerve bundle in surgical procedures. In packaged set configurations, the Solo-Dex Fascile® Continuous Peripheral Nerve Block Set, consisting of the peripheral nerve block needle, catheter, and related peripheral nerve block procedural accessories, is intended to provide continuous and/or intermittent infusion of local anesthetics and analgesics for peripheral plexus anesthesia and pain management during pre-operative, peri-operative and post-operative periods associated with surgical procedures. The catheter may remain indwelling for up to 72 hours.	The Contiplex C Continuous Peripheral Nerve Block Needle is intended for use in regional anesthesia and pain therapy to locate peripheral nerves by transferring electrical impulses from a nerve stimulator or by ultrasound visualization of the device. The needle is used to inject and facilitate the continuous administration of local anesthetics or analgesics to the target nerve bundle in general and orthopedic surgery. In set configuration, the B. Braun Contiplex C Continuous Peripheral Nerve Block Set, consisting of the peripheral nerve block needle catheter, and related peripheral nerve block procedural accessories, is intended to provide continuous and/or intermittent infusion of local anesthetics and analgesics for peripheral plexus anesthesia and pain management during pre-operative, perioperative, and post-operative periods associated with general and orthopedic surgery. The catheter may remain indwelling for up to 72 hours.	Substantially Equivalent
Technological Characteristics			
Basic Design	This is an over the needle catheter system.	This is an over the needle catheter system.	Substantially Equivalent

Parameter	Solo-Dex Fascile® Continuous Peripheral Nerve Block Catheter and Needle Kit 510(k) - (K151072)	Complex® C Continuous Peripheral Nerve Block Needle 510(k) (K121846), B. Braun Medical, Inc.	Comparison Substantially Equivalent or Equivalent
Principle of Operation: Nerve Location	The *proposed* device incorporates two methods for locating the targeted nerve bundle: (1) Stimulation and (2) Ultrasonic. Both devices are used for placing an indwelling catheter in position local to the target nerve.	The *predicate* device incorporates two methods for locating the targeted nerve bundle: (1) Stimulation and (2) Ultrasonic. Both devices are used for placing an indwelling catheter in position local to the target nerve.	Substantially Equivalent
Primary Difference Between Two Devices	1. Fascile utilizes multiple catheter / needle lengths (70 mm, 100 mm and 150 mm) based on the kit configuration. A clinician selects the appropriate needle/catheter lengths based on the location of the nerve block site. 2. Fascile kits include 3, 5 and 20 ml syringes and (2) hypodermic needles as accessories for clinician use if desired. 3. Fascile kits provide securement device(s) for the *catheter* after placement.	1. Contiplex C utilizes a dedicated length catheter / needle length of 188 mm. The clinician adjusts the catheter / needle length, based on the location of the nerve block site, using the provided C-Clip positioning device. 2. Contiplex C kits do not include syringes or hypodermic needles as accessories for clinician use. 3. Contiplex C kits provide a securement device for the *filter* after catheter placement.	Substantially Equivalent in terms of form, fit, function
Configuration	Fascile has a primary Catheter and Needle combination along with supporting accessories. The typical kit configuration includes syringes, needles, securement devices, filter and extension set. Except for the extension set, all accessories are off the shelf items.	Contiplex C has a primary Catheter and Needle combination along with supporting accessories. The Contiplex C kit configuration includes an extension set, filter and securement device.	Substantially Equivalent
<u>Primary Needle</u>			
Echogenic Needle	Fascile Needle is designed to be Echogenic. Needle is made from stainless steel.	Needle is designed to be Echogenic. Needle is made from stainless steel.	Substantially Equivalent
Needle Stimulation: Conductivity	Fascile Needle provides conductivity by means of a cable and external current source.	Contiplex C Needle provides conductivity by means of an integrated cable and external current source.	Substantially Equivalent
Needle Sharp (Penetration)	Fascile Needle is sharp enabling a clinician to penetrate tissue. Needle tip: Touhy.	Contiplex C Needle is sharp enabling a clinician to penetrate tissue. Needle tip: block bevel.	Substantially Equivalent
Needle and Catheter Hub Bond Strength	Conforms to ISO- 10555, Intravascular Catheters- Sterile and single Use Catheters – Part 1: General Requirements	Bond Strength testing is claimed in 510(k) Summary	Substantially Equivalent
<u>Primary Catheter</u>			

Parameter	Solo-Dex Fascile® Continuous Peripheral Nerve Block Catheter and Needle Kit 510(k) - (K151072)	Complex® C Continuous Peripheral Nerve Block Needle 510(k) (K121846), B. Braun Medical, Inc.	Comparison Substantially Equivalent or Equivalent
Primary Catheter Design	The catheter has an open end with side ports facilitating drug delivery. The catheter has a curved distal tip designed to keep the catheter near the nerve.	Contiplex C catheter has an open end at the tip for drug delivery.	Substantially Equivalent
Catheter Material	Catheter is made from a flexible plastic material.	Catheter is made from a flexible plastic material.	Substantially Equivalent
Depth Marks	Catheter is printed with depth marks.	Catheter is printed with depth marks.	Substantially Equivalent
Curvature to Position Around the Nerve(s)	The catheter curvature allows the catheter to remain close to the nerve.	Contiplex C is a straight catheter.	Substantially Equivalent in terms of form, fit, function
Other Components			
Extension Set – not made with Diethylhexylphthalate (DEHP)	Yes	Yes	Substantially Equivalent
Single, Single Use, and Disposable	Yes	Yes	Substantially Equivalent
Performance Data			
Biocompatibility (Externally Communicating Devices (needle, Catheter, and Extension Set)	Conformance to ISO 10993-1. Needle testing for limited exposure (<24 hours) and Catheter testing for prolonged exposure (>24hrs and <30 days).	Conformance to ISO 10993-1. Needle testing for limited exposure (<24 hours) and Catheter testing for prolonged exposure (>24hrs and <30 days).	Substantially Equivalent
Stimulation conductivity test	Conductivity test passed.	Conductivity claimed in 510(k) Summary.	Substantially Equivalent
Kink Resistance	Passed EN-13868.	Passed EN-13868.	Substantially Equivalent
Leakage	Passes ISO-594-1 and ISO-594-2 requirements for conical fitting. Luer junction was tested for leak tests.	Passes ISO-594-1 and ISO 594-2 requirements for conical fitting. Luer junction was tested for leak tests.	Substantially Equivalent
Human Factors: Simulated Use Test	Qualified clinicians participating in the Human factors study confirmed the usability of the Fascile kits.	Not available.	
Bond Strength and Pull Strength	Meets ISO 10555-1.	Not available.	
Needle Resistance to Corrosion	Needle complies with ISO-7864 and ISO-9626 and is manufactured from stainless steel.	Needle complies with ISO-7864 and ISO-9626 and is manufactured from stainless steel.	Substantially Equivalent
Flow Performance and Pump Compatibility	Catheter flow rate complies with ISO 10555-5 acceptance criteria (catheter flow between 90% and 115%). Flow restriction is 1% or less.	Not available.	Assumed Substantially Equivalent
Single Use, Sterile	Fascile kits are labeled single use only and sold sterile.	Contiplex C kits are labeled single use only and sold sterile.	Substantially Equivalent
Tubing - not made with Diethylhexylphthalate (DEHP)	All components not made with Diethylhexylphthalate (DEHP).	Labeled as “not made with Diethylhexylphthalate (DEHP)”	Substantially Equivalent

Parameter	Solo-Dex Fascile® Continuous Peripheral Nerve Block Catheter and Needle Kit 510(k) - (K151072)	Complex® C Continuous Peripheral Nerve Block Needle 510(k) (K121846), B. Braun Medical, Inc.	Comparison Substantially Equivalent or Equivalent
Drug Compatibility Requirement (Catheter and Extension Set)	Drug study has demonstrated Fascile is compatible for use with local anesthetic agent (Ropivacaine HCL 2 mg/ml). Fascile is used for Pain Management and delivery of anesthetic agents for regional anesthesia and pain management.	Contiplex C is designed for Pain Management therapy and delivery of anesthetic agents. Drug compatibility data is not available.	Assumed Substantially Equivalent
Packaging Testing	Product meets packaging tests per ISTA 2A.	Not available.	Assumed Substantially Equivalent

The differences that are identified in the table above were mitigated and addressed through product performance evaluations. The results are summarized in the Performance Data as given in the tables below.

VIII. PERFORMANCE DATA:

Biocompatibility Testing: Solo-Dex Fascile® Continuous Peripheral Nerve Block Catheter/Needle Kit

Test	Meets Specific ISO Standard Requirements (Pass/Fail)
L929 Neutral Red Uptake Cytotoxicity Test	**PASS**
Intracutaneous Injection Test	**PASS**
Kligman Maximization Test	**PASS**
Systemic Injection Test	**PASS**
Rabbit Pyrogen Test	**PASS**
Hemolysis - Rabbit Blood Indirect Contact	**PASS**
Salmonella typhimurium and *Escherichia coli* Reverse Mutation Assay	**PASS**
Mouse Lymphoma Mutagenesis Assay with Confirmation	**PASS**
Rodent Blood MIcronucleus Assay Repeat Dose	**PASS**
28-Day systemic Toxicity in Rats via Subcutaneous Implantation	**PASS**
Intramuscular Implantation Test	**PASS**

Table Summary of Bench (Performance) Testing

Test Document #	Title	Bench Test Description	Acceptance criteria	Result
TM-0001	Needle & Catheter Echogenicity Test Method	Confirm needle/catheter echogenicity via ultrasound	The test subject shall be visible in the ultrasonic machine.	Pass
TM-0002	Needle Electro-Stimulation Test Method	Confirm needle will transmit an electronic signal observed on a RMS multi-meter	In all current settings of stimulator from low 0.1 to high 5.0mA, the Fascile needle shall be able to transmit the signal as observed on the RMS multi-meter	Pass
TM-SR004A	Needle Sharpness Inspection	Visual and dimensional inspection for needle sharpness	Continuity of needle tip / edge no deformation.	Pass
TM-0005	Tensile Strength Test Method	Measure needle and catheter tensile strength	Fascile catheter body: Tensile strength for 18Ga ≥ 2.25 lbf. Tensile strength for 16GA ≥ 2.25 lbf Fascile catheter hub: Tensile strength for 18Ga ≥ 2.25 lbf. Tensile strength for 16GA ≥ 2.25 lbf Fascile needle hub:	Pass

			Tensile strength for 20Ga ≥ 12.14 lbf. Tensile strength for 18GA ≥ 2.25 lbf Fascile Bond strength: ≥ 2.25 lbf	
Test Document #	**Title**	**Bench Test Description**	**Acceptance criteria**	**Result**
TM-0008	Catheter and Extension Set Flow Test Method	Measure fluid flow rate through the extension set and catheter	Flow through predefined holes of a Fascile catheter is visible. Flow through Fascile catheter and extension set attached to a flow control tubing (test) does not drop below 20% compared to the flow of a flow control tubing alone (control).	Pass
TM-SR008A	Catheter Depth Mark Inspection	Visual and dimensional inspection for catheter depth marks	Depth marks exist and marking gaps meet drawing.	Pass
TM-SR009A	Catheter Curvature Inspection	Visual and dimensional inspection of catheter curvature	Correctness of curve orientation respect to arrow on hub.	Pass
TM-SR044A	Straightener Tube Test	Check for straightener tube functionality	Needle easily moves through the catheter without damage.	Pass
ISO 594-1:1986	Conical Fittings with a 6% (Luer) Taper for Syringes, needles and Certain other Medical Equipment – Part 1	ISO standard test methods for ensuring leak free fluid connectors	Complies with the ISO standard	Pass
ISO 594-2:1998	Conical Fittings with a 6% (Luer) Taper for Syringes, needles and Certain other Medical Equipment – Part 2	ISO standard test methods for ensuring leak free fluid connectors	Complies with the ISO standard	Pass

IX. SUMMARY OF ANIMAL AND CLINICAL STUDIES RESULTS:

Animal Study:

The Solo-Dex Fascile® Continuous Peripheral Nerve Block Catheter and Needle Kit does not require animal performance testing. There are no animal testing requirements for this Class II product.

Clinical Study:

The Solo-Dex Fascile® Continuous Peripheral Nerve Block Catheter and Needle Kit does not require a clinical study. There are no clinical study requirements for this Class II product.

CONCLUSION:

Based on the results of biocompatibility and performance testing, the proposed Solo-Dex Fascile® Continuous Peripheral Nerve Block Catheter and Needle Kit is considered substantially equivalent to the predicate device and as safe, as effective, and performs as well as the legally marketed (predicate) device.