August 13, 2021

Innovative Health Sciences, LLC
Shepard Bentley
Official Correspondent
1108 Kings Highway, Suite 4
Chester, New York 10918

Re: K202279
Trade/Device Name: Insignis Subcutaneous Needle Sets
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular administration set
Regulatory Class: Class II
Product Code: FPA
Dated: June 30, 2021
Received: July 8, 2021

Dear Shepard Bentley:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Payal Patel
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202279

Device Name
Insignis® Subcutaneous Needle Sets

Indications for Use *(Describe)*
Insignis® Subcutaneous Needle Sets are intended for the delivery of medication to the subcutaneous tissue for use not to exceed 24 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.

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510k Summary
K202279

Submitter

Innovative Health Sciences LLC

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Contact: Andy Sealfon

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Date Prepared: August 2, 2021

Official Correspondent

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Contact Person: Shepard G. Bentley, RAC

Name of Device: Insignis® Subcutaneous Needle Sets

Common or Usual Name: Subcutaneous Needle Set

Classification Name: Intravascular Administration Set

Classification Regulation: 21 CFR 880.5440

Regulatory Class: II

Product Code: FPA

Classification Panel: General Hospital

Predicate Device: RMS Subcutaneous Needle Set (K102512)

Device Description

The Insignis® Subcutaneous Needle Sets are sterile, single use, packaged subcutaneous needle sets. Each Subcutaneous Needle Set has a luer lock at one end and a 90-degree 26G (0.46mm) needle mounted to a closing wing-stabilizer (or butterfly wings) at the distal end of one or more needles. The needles are available in four different lengths: 6mm, 9mm, 12mm, and 14mm. Each set has a slide clamp to stop the flow immediately as well as a butterfly wing that can be closed around the needle upon completion of the infusion. The Insignis® Subcutaneous Needle Sets is available as a single set, as well as a two, three and four needles sets.

The Insignis® Subcutaneous Needle Sets is designed to be used for less than 24 hours

Intended Use

The Insignis® Subcutaneous Needle Sets are used to administer fluids from a container to a patient's subcutaneous tissues.

Indications for Use

Characteristics	Subject Device Insignis® Subcutaneous Needle Set K202279	Predicate Device: RMS Subcutaneous Needle Set (K102512)	Comment
Indications for Use	Insignis® Subcutaneous Needle Sets are intended for the delivery of medication to the subcutaneous tissue for use not to exceed 24 hours.	RMS Subcutaneous Needle Sets are intended for the delivery of medication to the subcutaneous tissue for use not to exceed 24 hours.	same
RX or OTC	Rx	Rx	same

There is no difference in intended use or Indications for Use between the subject device and the predicate device.

Summary of Technological Characteristics

	Subject Device Insignis® Subcutaneous Needle Set	Predicate Device: RMS Subcutaneous Needle Set	Comment

	K202279	(K102512)	
Intended Use/Indications for Use	Insignis® Subcutaneous Needle Sets are intended for the delivery of medication to the subcutaneous tissue for use not to exceed 24 hours.	RMS Subcutaneous Needle Sets are intended for the delivery of medication to the subcutaneous tissue for use not to exceed 24 hours.	Same
Duration of use	24 hours	24 hours	Same
Intended population	Adults and pediatrics	Adults and pediatrics	Same
Environment of use	Hospital, clinic, long-term care, home use	Hospital, clinic, long-term care, home use	Same
Sterility	SAL 10^{-6}	SAL 10^{-6}	Same
Sterilization Method	E-beam	Gamma	**Different** Comment #1
Single Use?	Yes	Yes	Same
Tubing Length (in)	24	20	**Different** Comment #2
Tubing Material	TPE	PVC	**Different** Comment #3
Needle Material	Stainless Steel	Stainless Steel	Same
Needle Gauge	26	26	Same
Needle Length (mm)	6, 9, 12, 14	6, 9, 12	**Different** Comment #4
Number of sets	1-4 needle sets	1-6 needle sets	**Different** Comment #5
Female Luer	Polypropylene (PP)	PVC	**Different** Comment #6
Butterfly	Polypropylene (PP)	Polypropylene	Same
Shelf Life	1 year	3 years	**Different** Comment #7
Biocompatibility	Per ISO 10993-1	Per ISO 10993-1	Same

The following differences are discussed:

Comment #1 Sterilization method: Both devices apply radiation sterilization and utilize the VD Max method of ensuring terminal sterility; however, the E-beam approach provides a focused method that allows an identical level of sterility as the alternative Gamma approach which relies upon a proximity method to a radioactive source. The outcomes from each method allow undifferentiated sterility, although the E-beam results in less yellowing of the material, generally.

Comment #2-Tubing Length: The subject device is 24 inches as compared to the predicate device which is 20 inches, and the difference in the length of the subject device tubing does not represent a change in performance and is based upon patient feedback since the debut of the predicate device.

Comment #3-Tubing Material: The subject device uses TPE while the predicate device uses PVC, as either material allows for biocompatibility and the same performance of the tubing. The TPE is less stiff and easier to use than PVC.

Comment #4-Needle Length: The subject device offers an extra needle set length of 14 mm, which itself represents the only difference from the predicate device, as the other needle lengths at 6 mm, 9 mm and 12 mm are identical. The subject device's extra set with a longer length nevertheless represents a substantially equivalent overall set of needle length options, and represents comparable performance, in view of the fact that the predicates of the predicate all had 14 mm length needle sets, as well. Presently, the predicate device offers the 14 mm needle length.

Comment #5-Number of Sets: The subject device has four sets versus the six sets of the predicate device; however, the overall performance remains comparable with regard to infusion volumes, as the volume of drug per site has increased since the predicate device was cleared.

Comment #6-Female Luer: The subject device luer material is polypropylene (PP) and the predicate device luer material is PVC; however, the materials provide comparable performance of the luer fittings.

Comment #7-Shelf Life: The subject device has been tested to one year of shelf life, whereas the predicate device has been tested to three years of shelf life. Within the respective shelf lives of the devices, no difference between the performance of the subject device and the predicate device pertains.

The information provided in the premarket notification demonstrates that the subject device, Insignis® Subcutaneous Needle Sets, are substantially equivalent to the legally marketed predicate device.
The subject device and the predicate device are intended to be used for the infusion of fluids into the body below the surface of the skin when attached to a fluid reservoir. Insignis® subcutaneous Needle Sets are identical in performance, physical properties, using similar materials and having the same indications for use as the predicate device. Each device includes needle sets with butterfly wings, tubing, clamps and luer connectors. The differences described above do not raise new or different questions of safety and effectiveness.

Performance Data

The following standards were applied for performance testing
ISO 9626:1991/AMD1:2001 Stainless steel needle tubing for the manufacture of medical devices – requirements and test methods
ISO 10993-1:2018 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a risk management process
ISO 10993-2:2006 Biological Evaluation of Medical Devices – Part 2: Animal Welfare requirements
EN ISO 10993-5:2009 Biological Evaluation of Medical Devices – Part 5: Test for in vitro cytotoxicity
ISO 10993-6:2016 Biological Evaluation of Medical Devices – Part 6: Tests for local effect after implantation
ISO 10993-10:2010 Biological Evaluation of Medical Devices – Part 10: Tests for irritation and skin sensitization
EN ISO 10993-11:2018 Biological Evaluation of Medical Devices – Part 11: Tests for systemic toxicity
EN ISO 10993-12:2012 Biological Evaluation of Medical Devices – Part 12: Sample Preparation and reference material
EN ISO 11137-1: 2015 Sterilization of Health Care Products – Radiation – Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices (include. Amendment 1, 2013)
EN ISO 11137-2:2015 Sterilization of Health Care Products – Radiation – Part 2: Establishing the sterilization dose
ISO 11137-3:2017 Sterilization of Health Care Products – Radiation – Part 3: Guidance on dosimetric aspects of Development, validation, and routine control
EN ISO 11737-1:2006 Sterilization of Health Care Products – Microbial methods, Part 1: Estimation of the population of microorganisms (incl. Technical Corrigendum)
EN ISO 11737-2:2009 Sterilization of Health Care Products – Microbial methods, Part 2: Tests of sterility performed In the definition, validation and maintenance of sterilization process
AAMI TIR 29:2012 Guide for Process Characterization Control in Radiation Sterilization 0f Medical Devices
ISO 11607-1:2019 Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems
ISO 594-2: 1998Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment - Part 2: Lock fittings
ISO 28620:2020 Medical Devices – non-electrically driven portable infusion devices
ISO 23908:2013 Sharps injury protection – Requirements and test methods-Sharps protection features for single-use hypodermic needles, introducers for catheters and

needles use for blood sampling
ISO 7864:2016 Sterile hypodermic needles for single use – Requirements and test methods
ISO 8536-9:2015 Infusion equipment for medical use – {art 9: Fluid lines for single use with pressure infusion equipment
ISO 14971:2019 Medical Devices-App
IEC 62366-1:2015 Medical Devices – Part 1: Application of Usability Engineering to Medical Devices

The needle sets described in this summary were tested and demonstrated to be in conformance with the following standards:

- ISO 9626:2001 Stainless steel needle tubing for the manufacture of medical devices-requirements and test methods
- ISO 594-2:
- Simulated clinical Use
- ISO 23908:2011
- PKP testing with various fluids
- Butterfly opening Force test
- Butterfly Low memory Test
- Fluid flow rates
- Pull force testing

Biocompatibility Testing

In accordance with ISO 10993-1, the subcutaneous needle sets are classified as: Externally communicating device, Blood Path indirect, Limited Contact (<24 hours). The following testing was conducted:

- ISO 10993-5:2009
- ISO 10993-6:2016
- ISO 10993-10:2010
- ISO 10993-11:2018

Sterility/Shipping/Shelf life

- Standard -package integrity testing/transportation
    - ISO 11607-1:2019

- Sterile barrier package testing
    - ISO 11607-1:2019
- Shelf life of 1 year validation
    - Real time aging
    - ISO 11607-1:2019

Conclusions

The differences between the predicate and the subject devices do not raise any new or different questions of safety or effective. The Insignis® Subcutaneous Needle Sets are substantially equivalent to the RMS Subcutaneous Needle Set (K102512) with respect to the indications for use, target population, and technological characteristic.