October 14, 2021

Intera Oncology, Inc.
% Sheila Hemeon-Heyer
President
Heyer Regulatory Solutions LLC
125 Cherry Lane
Amherst, Massachusetts 01002

Re: K211121
Trade/Device Name: Intera Non-coring (Huber) Refill Needles, Intera Non-coring (Huber) Special bolus Needles and OR Prep Kit
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: PTI
Dated: September 14, 2021
Received: September 15, 2021

Dear Sheila Hemeon-Heyer:

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,

For 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K211121

Device Name

Intera Non-coring (Huber) Refill Needles, Intera Non-coring (Huber) Special bolus Needles and OR Prep Kit

Indications for Use *(Describe)*

The Intera Non-coring (Huber) Needles (Refill Needles and Special Bolus Needles) and OR Prep Kit are indicated for use with the Intera implanted infusion pumps to administer infusate solutions.

Specifically,

- the Refill Needles are indicated for emptying and refilling the reservoir of an Intera 3000 Hepatic Artery Infusion Pump or CODMAN® 3000 Series Pump;
- the Special Bolus Needles are indicated for delivering bolus injections or infusions through an Intera 3000 Hepatic Artery Infusion Pump or CODMAN® 3000 Series Pump;
- the OR Prep Kit is used to prepare the Intera 3000 Hepatic Artery Infusion Pump or CODMAN® 3000 Series Pump prior to implantation.

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."

K211121 - 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted per the requirements of 21 CFR 807.92.

A. Submitter:

Intera Oncology, Inc.
65 Williams St, Suite 200
Wellesley, MA 02481
Contact: Michael Gaisford
Title: Chief Executive Officer
Tel #: 781-489-5724
Email: mgaisford@interaoncology.com

B. Date Prepared: October 14, 2021

D. Device Name and Classification Information:

Trade Name:	Intera Non-coring (Huber) Refill Needles Intera Non-coring (Huber) Special Bolus Needles OR Prep Kit
Common Name:	Non-Coring (Huber) Needle
Classification Name:	Hypodermic Single Lumen Needle
Classification:	21 CFR 880.5570
Product Code:	PTI
Review Panel:	General Hospital
Class:	II

E. Predicate Devices: K200463 Huber Needle Infusion Set

F. Summary Device Description:

The Intera Refill Needle is a straight 22 gauge stainless steel non-coring needle with hub and needle cap. The Refill Needle is available in 1", 1 ½", and 2" lengths and is used to empty and fill the reservoir of a subcutaneously implanted infusion pump through the pump septum. The Refill Needle is provided sterile and is intended for single patient use.

The Intera Special Bolus Needle is a straight 20 gauge stainless steel non-coring needle with hub and needle cap. A tubing extension set is integrated with the needle hub. The Special Bolus Needle is available in 1 3/8" and 2" lengths and is used to deliver infusate through the pump septum to the pump catheter. The Special Bolus Needle is provided sterile and is intended for single patient use.

The Intera OR Prep Kit contains the accessories used to prep and fill the pump prior to implantation and is assembled as a convenience to the end-user with the following sterile, single-use items:

- One (1) 22g non-coring (Huber) Refill Needle
- One (1) 20g non-coring (Huber) Special Bolus Huber Needle with attached tubing, clamp, and female luer
- One (1) 33cm (13”) tubing set with clamp and female luer assembled to an empty syringe barrel

The empty syringe barrel acts as a liquid waste receptacle to hold the fluid that is passively drained from the infusion pump during pump preparation prior to implantation. The empty syringe barrel and drained fluid are discarded after use and have no direct or indirect patient contact. The empty syringe barrel does not include a piston and does not function as a piston syringe.

G. Indications for Use Statement:

The Intera Non-coring (Huber) Needles (Refill Needles and Special Bolus Needles) and OR Prep Kit are indicated for use with the Intera implanted infusion pumps to administer infusate solutions.

Specifically,

- the Refill Needles are indicated for emptying and refilling the reservoir of an Intera 3000 Hepatic Artery Infusion Pump or CODMAN® 3000 Series Pump
- the Special Bolus Needles are indicated for delivering bolus injections or infusions through an Intera 3000 Hepatic Artery Infusion Pump or CODMAN® 3000 Series Pump
- the OR Prep Kit is used to prepare the Intera 3000 Hepatic Artery Infusion Pump or CODMAN® 3000 Series Pump prior to implantation.

H. Technical Comparison with Predicate Devices

The table below provides technological comparisons between the proposed and predicate devices. A discussion of the differences is provided following the table.

Table 1. Comparison of the Intera Huber Needle Set to the Predicate Huber Needle Set

Comparison Item	Proposed Device K211121	Predicate Device K200463	Assessment of Substantial Equivalence
Devices	Intera Non-coring (Huber) Refill Needle Intera Non-coring (Huber) Special Bolus Needle Intera OR Prep Kit	Huber Needle Infusion Set	N/A
Manufacturer	Intera Oncology, Inc.	Jiangsu Caina Medical Co., Ltd	N/A
FDA Product Code	PTI	PTI	Same
Class	II	II	Same
Indication for Use	The Intera Non-coring (Huber) Needles (Refill Needles and Special Bolus Needles) and OR Prep Kit are indicated for use with the Intera implanted infusion pumps to administer infusate solutions. Specifically, • the Refill Needles are indicated for emptying and refilling the reservoir of an Intera 3000 Hepatic Artery Infusion Pump or CODMAN® 3000 Series Pump • the Special Bolus Needles are indicated for delivering bolus injections or infusions through an Intera 3000 Hepatic Artery Infusion Pump or CODMAN® 3000 Series Pump • the OR Prep Kit is used to prepare the Intera 3000 Hepatic Artery Infusion Pump or CODMAN® 3000 Series Pump prior to implantation	The Huber Needle Infusion Set is a device with a non-coring right angle needle intended for insertion into the septum of a subcutaneously implanted port and for the infusion of fluids and drugs, as well as blood sampling into the port. The 19G-22G needles of device are also suitable for power injection of contrast media to a maximum pressure of 325psi. When used with ports indicated for power injection, the maximum recommended infusion rate is approximately 5ml/s for 19G and 20G, 2ml/s for 22G	See SE discussion

Comparison Item	Proposed Device K211121	Predicate Device K200463	Assessment of Substantial Equivalence
Use environment	Hospital or clinic setting	Hospital or clinic setting	Same
Intended users	Healthcare providers licensed to use Huber needles and infusion sets	Healthcare providers licensed to use Huber needles and infusion sets	Same
Components and materials of construction	Huber needles – 304 stainless steel PVC tube Clamps Male and female Luers Empty syringe barrel (no piston)	Huber needles – stainless steel PVC tube Clamps Male and female Luers Needle-less connector Y-needleless adapter Y-needle adapter	Different, see SE discussion in Section I and discussion of testing in Section J.
Hub/needle bond strength	≥ 15 lbf (66 N)	Unknown	Different. Intera needle/hub bond strength exceeds requirement of ISO 7864:2016. See Section J.
Needle tip configuration	Non-coring (Huber) tip, straight	Non-coring (Huber) tip, bent, 90˚ angle	Different, see SE discussion
Dimensions	Needle gauges: 20G, 22G Needle lengths: 1”, 1 3/8”, 1.5”, 2” Tubing set length: 33 cm	Needle gauges: 19G, 20G, 22G, 24G, 25G Needle lengths: 0.5”, 0.75”, 1”, 1.25”, 1.5” Tubing set: Unknown	Different, See SE discussion
Safety and Performance tests	Coring test Penetration force Occlusion testing Joint integrity/tensile testing Leak testing Needle performance Luer connector performance Particulates Biocompatibility Sterilization validation Transportation testing Shelf life testing	Coring test Penetration force Occlusion testing Joint integrity/tensile testing Leak testing Needle performance Luer connector performance Wing flexibility Particulates Biocompatibility Sterilization validation	Same except wing flexibility is not required for proposed device as it does not contain any wings. See Section J for discussion of Intera safety and performance tests.
Material safety	Complies with ISO 10993	Complies with ISO 10993	Same
Sterile	Yes, EtO, SAL 10^{-6}	Yes, EtO, SAL 10^{-6}	Same
Non-Pyrogenic	Yes	Yes	Same
Single Use	Yes	Yes	Same
Shelf life	24 months	Unknown	Different

I. Discussion of Differences

Indications for Use

Both the proposed and predicate devices are intended for insertion through the septum of subcutaneously implanted receptacles for infusion of fluids and drugs. The proposed device is used for infusion of an implanted infusion pump, while the predicate device is used for infusion of an implanted port. The predicate device is also used for blood sampling from the implanted port and for power injection, neither of which can be done with the proposed device. These differences do not raise new questions of safety or effectiveness because the indications for use of the proposed device are within those of the predicate device.

Infusion Set Components

Both the proposed and predicate devices include non-coring (Huber) needles, tubing, luers, and clamps. Some of the accessories in the two infusion sets differ, i.e., the predicate infusion set also includes connectors, wings, and Y-adapters, that are needed for its intended uses related to an implanted port, while the proposed infusion set includes an empty syringe barrel, which is needed for its intended uses related to an implanted infusion pump. The empty syringe barrel is provided as a convenience to the user and serves as a passive waste receptacle for bacteriostatic water that is removed from the pump prior to implantation. The empty syringe barrel is not a piston syringe and contains no piston as a piston is not needed to draw out the fluid. There is no patient contact with the empty syringe barrel, and both the barrel and removed fluid are discarded after use. The end of the empty syringe barrel is covered by a Tyvek seal, and leak testing conducted to an internal protocol (see Section J) confirmed the integrity of this seal. Even if the Tyvek seal were to leak, there would be no risk to the patient or user as: 1) this process occurs during pump preparation before pump implantation; 2) the operator will be wearing sterile gloves; and 3) the removed fluid is bacteriostatic water. Therefore, this additional infusion set accessory does not raise any new questions of safety or effectiveness.

Hub/Needle Bond Strength

The hub/needle bond strength for the predicate device is unknown. However, the hub/needle bond strength for the Intera needles was tested to and demonstrated to comply with the requirements of ISO 7864:2016 (See Section J). Therefore, any differences between the proposed and predicate devices do not raise any new questions of safety or effectiveness.

Huber Needle Tip Configuration

The Huber needles in the proposed device have a straight tip, while the Huber needles in the predicate device have a bent (90 degrees) tip. The straight tip of the Intera Huber needles is appropriate for accessing the Intera 3000 and Codman 3000 infusion pumps, which are implanted subcutaneously in the lower abdomen. A bent needle is not necessary for pump access. The Intera needles were tested to and shown to comply with the applicable requirements of ISO 7864:2016, ISO 9626:2016, and ASTM F3212-16 for stainless steel needles (see Section J). Therefore, this difference does not raise any new questions of safety or effectiveness for the Intera Huber needles.

Needle Gauge and Length

The needle gauges of the Intera Huber needles are within the range offered by the predicate device. The Intera Huber needle lengths are also within the range offered by the predicate device except that the largest Intera Huber needle is 2” as compared to 1.5” for the predicate. This longer length is only needed in the case of a larger patient where there may be a greater distance to reach the pump receptacle. All needle lengths function the same. The Intera needles were tested to and shown to comply with the applicable requirements of ISO 7864:2016, ISO 9626:2016, and ASTM F3212-16 for stainless steel needles (see Section J). Therefore, this difference does not raise new questions of safety or effectiveness.

Shelf Life

The shelf life for the predicate device is unknown. However, the 24-month shelf life for the Intera Non-coring (Huber) Needles and OR Prep Kit was established by testing samples that had been real-time aged under warehouse conditions in conformance with ASTM F1929-15 and ASTM F88M/F88-15 for package integrity and applicable requirements of ISO 7864:2016 and ISO 8536-9:2015 for device integrity (see Section J). Therefore, any differences between the proposed and predicate devices do not raise any new questions of safety or effectiveness.

J. Testing to Support Substantial Equivalence

Performance Testing

The table below presents all of the bench performance tests conducted to support this 510(k). All tests met or exceeded the acceptance criteria of the applicable standards. No animal or clinical testing was conducted.

Test Standard	Tests Conducted	Test Acceptance Criteria
ISO 7864:2016 Sterile Hypodermic Needles for Single Use - Requirements and Test Methods	Visual inspections	Outside surface of the tubing shall be smooth and free from defects. Needle tube shall appear straight and of regular roundness. Surfaces of the tubing shall be free from metal soil and processing agents.
	Needle length tolerance verification	Needle length shall be within +1.5 mm/-2.5 mm of the nominal length.
	Tensile Testing of needle/hub connections	Cannula/Hub connection shall withstand a 15 lbf tensile load
	Patency of Flow Testing	Stainless steel stylet of 0.30 mm shall pass through the needle to the non-coring feature.
	Drag/Penetration force testing	Maximum Drag/Penetration force of 5 lbf.

Test Standard	Tests Conducted	Test Acceptance Criteria
	Acidity / Alkalinity testing	Extract PH shall be within one unit of pH of that of the control fluid.
	Extractables testing	Limit of 5 mg/L of lead, tin, zinc, and iron. Limit of 0.1 mg/L of cadmium.
ISO 9626:2016 Stainless Steel Needle Tubing for The Manufacture of Medical Devices - Requirements and Test Methods	Stiffness testing	Maximum deflection of 0.42 mm.
	Resistance to breakage testing	No visible breakage.
	Corrosion testing	No visible sign of corrosion.
ASTM F3212-16 Standard Test Method for Coring Testing of Huber Needles	Non-Coring Testing	Absence of core in the needle cannula
ISO 8536-9:2015 Infusion Equipment for Medical Use - Part 9: Fluid Lines for Single Use with Pressure Infusion Equipment	Leak Testing	Cannula/Hub connection shall maintain leak integrity when a pressure of 45 psi
	Tensile testing of tubing luer connections	Each joint in the device shall withstand a tensile for of 5 lbs
	Leak testing of tubing luer connections	Flow path shall withstand a minimum of 50 psig of air
ISO 594-1:1986 and ISO 594-2:1998 Conical Fittings With 6 % (Luer) Taper for Syringes, Needles and Certain Other Medical Equipment – Part 1: General Requirements and Part 2: Lock Fittings	Luer performance testing	The connectors fit within the limits of the gauge. No observed leakage sufficient to form a falling drop of water. Connectors remained attached under 35 N load. Connectors remained attached under 0.020 N·m unscrewing torque. Connectors successful connected to the reference fitting/male luer. Connector did not override threads under load. No signs of stress cracking observed.

Test Standard	Tests Conducted	Test Acceptance Criteria
USP <788> Particulate Matter in Injections	Particulate testing	Average number of particles present does not exceed 6000 per device equal to or greater than 10 µm and does not exceed 600 per device equal to or greater than 25 µm.
Internal Intera Protocols	Clamp Flow Stoppage and Release Testing	Clamp shall prevent water at 45 psig from flowing once clamped for 2 minutes. Upon release of the clamp, water at 5 psig must flow through the clamped section.
	Leak Testing (Syringe Barrel Lid)	No leakage when inverted with 18 mL of water present

Sterilization Validation

Ethylene oxide sterilization was validated to a Sterility Assurance Level (SAL) of 10^{-6} using the half-cycle, overkill method per ISO 11135:2014, 2nd edition, Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation, and routine control of a sterilization process for medical devices. Bacterial endotoxin testing conducted using the LAL Test per USP 40-NF35:2017 <85> Bacterial Endotoxins Test confirmed endotoxin levels well below the limit of the standard (<20.0 EU/Device), Sterilization residuals were evaluated according to ISO 10993-7:2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals and were found to be below the maximum allowed levels of the standard after aeration.

Biocompatibility

The following biocompatibility tests were conducted to support this 510(k):

- Cytotoxicity per ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- Sensitization and Irritation per ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- Acute systemic toxicity per ISO 10993-11:2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- Material-mediated pyrogenicity per USP 40-NF35:2017 <151> Pyrogen Test (USP Rabbit Test)
- Hemocompatibility per ISO 10993-4:2017 Biological evaluation of medical devices-- Part 4: Selection of tests for interactions with blood, including hemolysis per ASTM

F756-17 Standard Practice for Assessment of Hemolytic Properties of Materials (indirect), and hemocompatibility

Shelf-Life Validation Testing

The following package validation and shelf life testing was completed on final, finished EtO sterilized samples that had been real-time aged for at least 25 months.

- Transportation testing according to ISTA 3A for Packaged-Products for Parcel Delivery System Shipments 70kg (150 lb) or Less (standard, small, flat or elongated)
- Package integrity testing, including the dye penetration test per ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration and the seal strength test per ASTM F88M/F88-15 Standard Test Method for Seal Strength of Flexible Barrier Materials
- Device integrity testing, including tensile strength and leak testing

K. Conclusion

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The information and testing presented in this 510(k) demonstrate that the Intera Non-coring (Huber) Refill and Special Bolus Needles and OR Prep Kit with Tubing Set are substantially equivalent to the Huber Needle Infusion Set cleared under K200463 with respect to the indications for use and technological characteristics.