April 27, 2022

Curatia Medical Co.
℅ Breanne Butler
Regulatory Affairs Consultant
Prime Path Medtech
1321 Upland Dr. Suite 6792
Houston, Texas 77043

Re: K220604
Trade/Device Name: EXTesia Introducer Sheath Set
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: March 2, 2022
Received: March 2, 2022

Dear Breanne Butler:

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,

Misti Malone
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular 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)*
K220604

Device Name
EXTesia Introducer Sheath Set

Indications for Use *(Describe)*
The EXTesia Introducer Sheath Set is intended to be inserted percutaneously into a vessel to facilitate placing the interventional or diagnostic devices into a vein or artery.

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.

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510(k) Summary

A summary of 510(k) information in accordance with the requirements of 21 CFR 807.92.

Submitter: Curatia Medical Co

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Submission Correspondent: Breanne Butler, Regulatory Affairs Consultant
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Date Prepared: February 2022

Proprietary Name: EXTesia Introducer Sheath Set

Common Name: Introducer Sheath

Product Code: DYB

Device Classification: Class 2

Predicate Device: Terumo Medical Glidesheath Slender
Reference Device: Terumo Medical Radifocus Introducer Kit

Device Description:

The EXTesia Introducer Sheath Set is used to facilitate placing a catheter through the skin into a vein or artery. The set consists of an introducer (a sheath and a dilator) packaged together with an entry needle, guide wire, flushing syringe, and scalpel. The sheath and dilator contain a radiopaque material which makes these devices visible under fluoroscopy. In addition, the sheath is coated with hydrophilic coating to minimize frictional resistance when inserting or removing the sheath from the patient's blood vessel.

EXTesia Introducer Sheath Set is packaged in a Tyvek 1073B pouch, sealed, labelled and EtO sterilized. It is for single use only. The EXTesia Introducer Sheath Set is designed for 3 years shelf life.

Indications for Use:

The EXTesia Introducer Sheath Set is intended to be inserted percutaneously into a vessel to facilitate placing the interventional or diagnostic devices into a vein or artery.

Comparison to Predicate Devices:

EXTesia Introducer Sheath Set is similar in design, construction, and performance characteristics to the following commercially available world leading products: RADIFOCUS Introducer II Kit and Glidesheath Slender Introducer Sheath Kit, manufactured by Terumo Corporation (K954234, K173831):

- Same indication for use
- Same product code, regulations and class
- Same target population
- Same components
- Same guide wire types/OD, entry needle types/OD, syringe capacity and scalpel specifications
- Similar sheath size, sheath length and dilator length
- Similar materials
- Same sterile barrier system and method of sterilization
- Same biocompatibility testing

Performance Testing

Testing was conducted to validate the biocompatibility, sterilization, mechanical integrity, functionality, and product specifications of the EXTesia Introducer Sheath Set. Each individual component was subjected to individual testing as well the entire working system as well. Simulated Usability testing was also completed and passed by the EXTesia Introducer Sheath Set. These studies were completed successfully and the EXTesia Introducer Sheath Set has been validated to maintain its mechanical integrity, functionality, and meets the requirements for product specifications during use within 3 years of shelf life.

Clinical Testing

No Clinical Testing was required for this product.

Statement of Equivalence

EXTesia Introducer Sheath Set

As summarized above, the main differences between the subject (Curatia Medical – EXTesia Introducer Sheath Set) and predicate and reference devices (Terumo Corporation – RADIFOCUS Introducer II Kit and Glidesheath Slider) are:

- Sheath Dimensions
- Dilator Length
- Predicate devices use Bismuth Trioxide as a material

Based on comparison of indications for use, user population, performance testing, mechanical and technological features, the EXTesia Introducer Sheath Set has been shown to be substantially equivalent to the legally marketed predicate device. This device does not raise any new safety or effectiveness questions as compared to the predicate device.