December 14, 2018

Curatia Medical Co.
% Breanne Butler
Regulatory Affairs Consultant
JCQ Consulting
11218 Zest Court NE
Blaine, Minnesota 55449

Re: K180797
Trade/Device Name: Xcess Guiding Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: November 15, 2018
Received: November 15, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Lydia S. Glaw -S

Digitally signed by Lydia S. Glaw -S
Date: 2018.12.14 15:12:17 -05'00'

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular 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)*
K180797

Device Name
Xcess Guiding Catheter

Indications for Use *(Describe)*
The guiding catheter is intended to use for intravascular introduction of interventional/diagnostic devices into the coronary or peripheral vascular systems.

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

510(k) SUMMARY
K180797

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Date Prepared: December 13, 2018

Proprietary Name: Xcess Guiding Catheter

Common Name: Percutaneous catheter

Product Code: DQY

Device Classification: Class II, 21 CFR 870.1250 – Percutaneous Catheter

Predicate Devices: VISTA BRITE TIP Guiding Catheter (K962830)

Device Description:

The Xcess guiding catheter is available in many different curve shapes and two sizes (5F and 6F). Each device consists of a catheter shaft, soft extension, soft tip, strain relief and luer. The catheter shaft is constructed with 3 layers: an outer layer of radiopaque Nylon/Pebax material, a middle layer of braided stainless steel, and an inner layer of PTFE tubing. The soft extension and soft tip consist of 2 layers: an outer layer of a radiopaque Nylon/Pebax material of differing hardness than the layer in the catheter shaft and an inner layer of PTFE. The strain relief at the proximal end of the catheter prevents kinking during catheter manipulation, and the luer is used to connect with either a hemostasis valve-linked accessory or 3-way connector. The distal ends of the guiding catheters are formed into a variety of shapes required to access differing vasculatures. The guiding catheters are provided with a hydrophilic coating on the catheter body. The guiding catheters are designed to accept a maximum of 0.038" (0.97mm) diameter guide wire.

Indications for Use:

The guiding catheter is intended to use for intravascular introduction of interventional/diagnostic devices into the coronary or peripheral vascular systems.

Comparison to Predicate Devices:

The Xcess Guiding Catheter is substantially equivalent in design, construction, and performance characteristics to the following commercially available product: VISTA BRITE TIP Guiding Catheters (CORDIS – FDA registration No: K962830, 1996). Based on comparison and testing of the predicated device and the Xcess Guiding Catheter, the specifications of the Xcess Guiding Catheter (Curatia) are substantially equivalent to the predicate device, VISTA BRITE TIP Guiding Catheter (Cordis). The clinical, technical, material, and biological specifications of the Xcess Guiding Catheter are substantially equivalent to the predicate device.

Summary of Performance Data and Substantial Equivalence:

The Xcess Guiding Catheters were designed and verified in accordance with the risk analysis and product requirements. All tests confirmed the products met the pre-defined acceptance criteria. Curatia Medical has determined that the Xcess Guiding Catheters are substantially equivalent. The Xcess Guiding Catheters have been tested and shown to be compliant with the following standards documents:

- ISO 10555-1:2013- Intravascular catheters – Sterile, single-use intravascular catheters – Part 1: General requirements
- ISO 10993-1:2009- Biological evaluation of medical devices – Part 1: Evaluation and testing
- ISO 10993-3:2014- Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
- ISO 10993-4:2002+AMD1:2006-Biological testing of medical and dental materials and devices – Part 4: Selection of tests for interactions with blood
- ISO 10993-5: 2009- Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010 – Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization
- ISO 10993-11:2006- Biological testing of medical and dental materials and devices – Part 11: Tests for systemic toxicity
- ISO 10993-12:2012- Biological testing of medical and dental materials and devices – Part 12: Sample Preparation And Reference Materials
- ISO 11135: 2014 Sterilization of health-care products-Ethylene oxide–Requirements for the development, validation and routine control of a sterilization process for medical devices
- EN ISO 11607-1: 2009(R2014)- Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems

Performance Testing:

To demonstrate substantial equivalence of the Xcess Guiding Catheter to the predicate device, the technological characteristics and performance criteria were evaluated using the bench testing recommendations outlined in the ISO 10555-1 Sterile, single-use intravascular catheters-Part 1: General requirement. The following performance tests were completed:

- Visual and dimension inspection
- Coating integrity and particulate evaluation
- Catheter usability

- Catheter shape retention
- Catheter freedom from leakage
- Catheter torque
- Catheter pressure integrity
- Catheter flexibility and kink
- Catheter joints tensile strength
- Corrosion resistance
- Radio-detectability

The results of these tests demonstrate that the technological characteristics and performance criteria of the Xcess Guiding Catheter are adequate for its intended use, and that is substantially equivalent to the predicate device.

Biocompatibility:

To demonstrate the biocompatibility of the materials in contact with the body and substantial equivalence of the Xcess Guiding Catheter to its predicate device, the following biocompatibility testing was performed in accordance with ISO 10993 and the FDA Guidance Document "Use of International Standard ISO 10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing"" dated June 2016:

- Cytotoxicity
- Sensitization
- Irritation or Intracutaneous Reactivity
- Acute Systemic Toxicity
- Material-Mediated Pyrogenicity
- Hemocompatibility (Hemolysis, Thrombogenicity, and Complement Activation)

The results from these tests demonstrate that the Xcess Guiding Catheter is biocompatible for its intended use.

Conclusion:

Based on comparison of indications for use, technological characteristics, performance testing, biocompatibility testing, the Xcess Guiding Catheter has been shown to be appropriate for its indications for use and is substantially equivalent to the legally marketed predicate device.