July 16, 2020

Intrinsic Therapeutics, Inc.
Regina Shih
VP, Regulatory Affairs
30 Commerce Way
Woburn, Massachusetts 01801

Re: K201676
Trade/Device Name: Barricaid® Instrument Tray
Regulation Number: 21 CFR 888.4510
Regulation Name: Manual Surgical Instrument for Appropriate Patient Selection for Orthopedic Implant
Regulatory Class: Class II
Product Code: QHG
Dated: June 19, 2020
Received: June 19, 2020

Dear Regina Shih:

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,

Brent Showalter, Ph.D.
Acting Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic 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)*
K201676

Device Name
Barricaid® Instrument Kit

Indications for Use *(Describe)*

The Intrinsic Therapeutics Defect Measurement Tool for the Barricaid® Annular Closure Device is intended to aid in determining if a patient meets the indications for use defined for the Barricaid® Annular Closure Device by assessing the defect size in the annulus fibrosus following limited discectomy. This tool is indicated to only be used with the Intrinsic Therapeutics Barricaid® Annular Closure Device.

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.

510(k) Summary (21 CFR 807.92)

1. Submitter

Submitter Name: Intrinsic Therapeutics

Address: 30 Commerce Way, Woburn, MA 01801

Telephone: 781-932-0222

Contact Person: Regina Shih

E-mail: RShih@in-Thera.com

Date: July 14, 2020

II. Device Information

Device Name: Barricaid® Instrument Kit

Common Name: Defect measurement Tool

Classification Panel: Orthopedic

Regulation Number: 21 CFR 888.4510

Regulatory Class: 2

Product Code: QHG

III. Predicate Device

Primary Predicate: Defect Measurement Tool (Product Code QHG, Regulation 21 CFR 888.4510)

Reference Device: Barricaid® Annular Closure Device (ACD) – P160050

IV. Device Description

The Barricaid® Instrument kit contains a number of manual surgical instruments as well as the Defect Measurement Tool. This kit is provided with all of the instruments with a sterilization tray. The Defect Measurement Tool is intended to measure the annular defect to determine if a patient meets the indications for use for the Barricaid® Annular Closure Device. All instruments are made from stainless steel. This kit is intended to be used only with the Intrinsic Therapeutics Barricaid® Annular Closure Device (ACD).

The purpose of this submission is to modify and reduce the size of the sterilization tray used to contain the reusable instruments necessary to surgically implant or remove the Barricaid® Annular closure device.

V. Indications for Use

The Intrinsic Therapeutics Defect Measurement Tool for the Barricaid® Annular Closure Device is intended to aid in determining if a patient meets the indications for use defined for the Barricaid® Annular Closure Device by assessing the defect size in the annulus fibrosus following limited discectomy. This tool is indicated to only be used with the Intrinsic Therapeutics Barricaid® Annular Closure Device.

VI. Comparison of Technological Characteristics with the Predicate Device

The instruments included in the subject Barricaid® Instrument Kit are identical to the kit in the previously approved kit (P160050) and include the Defect Measurement Tools, Alignment Trials, Slotted Mallet, and the Retraction Wedge. The dimension of the sterilization tray is reduced from the predicate sterilization tray. The sterilization tray is comprised of stainless-steel, and the brackets composed of stainless-steel or silicone material, which is identical to the predicate.

VII. Performance Data

- Bench Testing

  Scientific evaluation of sterilization validation and cleaning validation based on worst case. Scientific evaluation of shipping condition based on worst case and market history.

- Clinical Testing

  No new clinical testing was performed.

- Biocompatibility

  No new biocompatibility testing was performed.

VIII. Conclusion

Based on the changes to the tray, the risk analysis, rationale and previous testing demonstrated that there are no additional risks that have been detected beyond acceptance level. The bench testing conducted supports the proposed device as substantially equivalent to the predicate device (Defect Measurement Tool (Product Code QHG, Regulation 21 CFR 888.4510)).