DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Intrinsic Therapeutics, Inc.
c/o Glenn Stiegman
MCRA, LLC
1050 K Street NW, Suite 1000
Washington, DC 20001

May 28, 2019

Re: Q190378
Defect Measurement Tool for the Barricaid® Anular Closure Device
Evaluation of Accessory Classification Under Section 513(f)(6) – Accessory Classification Request
Regulation Number: 21 CFR 888.4510
Regulation Name: Manual Surgical Instrument for Appropriate Patient Selection for Orthopedic Implant
Regulatory Classification: Class II
Product Code: QHG
Dated: March 1, 2019
Received: March 4, 2019

Dear Glenn Stiegman:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your Accessory Classification request for classification of the Defect Measurement Tool for the Barricaid® Anular Closure Device, a prescription device that is indicated for the following:

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

FDA concludes that this device should be classified into class II. This order, therefore, classifies the Defect Measurement Tool for the Barricaid® Anular Closure Device, and substantially equivalent devices of this generic type, into class II under the generic name manual surgical instrument for appropriate patient selection for orthopedic implant.

FDA identifies this generic type of device as:

> **Manual surgical instrument for appropriate patient selection for orthopedic implant.** *Identification.* Orthopedic manual surgical instrument used to measure an anatomical feature(s) to determine appropriate patient selection for an orthopedic

implant. The characteristics of the instrument are defined by the specifications set for the orthopedic implant in terms of geometry, surgical technique and use of the device.

Section 513(f)(6) of the Federal Food, Drug and Cosmetic Act (the FD&C Act) was added by section 707 of the FDA Reauthorization Act of 2017 (FDARA) on August 18, 2017, and was effective on October 17, 2017 (Pub. L. 115-52). This provision establishes a pathway for manufacturers or importers to request classification of accessories distinct from another device upon written request. The classification is based upon the risks of the accessory when used as intended as well as the level of regulatory controls necessary to provide a reasonable assurance of safety and effectiveness, notwithstanding the classification of any other device with which such accessory is intended to be used. Until an accessory is reclassified by FDA, the classification of any accessory distinct from another device by regulation or written order issued prior to December 13, 2016 will continue to apply.

Under section 513(f)(6)(D)(ii) of the FD&C Act, a manufacturer or importer may request proper classification of an accessory that has been granted marketing authorization as part of a premarket approval application (PMA), premarket notification (510(k)), or De Novo classification request. FDA must grant or deny the request not later than 85 days after receipt and, if granting, publish a notice in the **Federal Register** within 30 days classifying the accessory type.

Alternatively, under section 513(f)(6)(C), a person filing a PMA or 510(k) may include a written request for the proper classification of an accessory that has not been classified distinctly from another device based on the risks of the accessory when used as intended and the level of regulatory controls necessary to provide a reasonable assurance of safety and effectiveness. When the written request is included in a submission for marketing authorization, FDA must grant or deny the request along with the response to the PMA or 510(k). Upon granting, FDA will publish a notice in the **Federal Register** within 30 days classifying the accessory.

FDA received your Accessory Classification request on March 4, 2019 to classify the Defect Measurement Tool for the Barricaid® Anular Closure Device into class II under section [choose 513(f)(6)(C) or 513(f)(6)(D)(ii)] of the FD&C Act. In order to classify the Defect Measurement Tool for the Barricaid® Anular Closure Device into class II, the proposed class must have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

After review of the information submitted in the Accessory Classification and the previous P160050 submission, FDA has determined that the Defect Measurement Tool for the Barricaid® Anular Closure Device indicated for the Indications for Use identified above can be classified in class II with the establishment of special controls. FDA has determined that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in Table 1.

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risk(s)	**Mitigation Measure(s)**
Adverse tissue reaction	Biocompatibility evaluation

Identified Risk(s)	Mitigation Measure(s)
Infection	Reprocessing validation Labeling
Improper assessment of size of defect	Nonclinical performance testing
Inadvertently enlarging the size of the defect	Nonclinical performance testing

In combination with the general controls of the FD&C Act, the manual surgical instrument for appropriate patient selection for orthopedic implant is subject to the following special controls:

(1) Technical specifications regarding geometry of the instruments must be identified and validated to demonstrate that the instruments accurately measure the critical geometry for patient selection of the intended orthopedic implant.
(2) The use of the instruments is validated to demonstrate that the measurement process does not alter the patient anatomy which is being measured.
(3) The patient contacting components of the device must be demonstrated to be biocompatible; and
(4) Labeling must include:
    (i.) Identification of orthopedic implant(s) and instruments which have been validated for use together; and
    (ii.)Validated methods and instructions for reprocessing any reusable parts.

Please be advised that FDA's decision to grant this Accessory Classification request does not mean that FDA has determined that your device complies with other requirements of the FD&C Act or any Federal statutes or regulations administered by other Federal agencies. You must comply with all applicable requirements under the FD&C Act, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD&C Act; 21 CFR 1000-1050).

A notice announcing this classification order will be published in the **Federal Register**. A copy of this order is on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may market your device as described in the Accessory Classification request, provided that your device complies with the general control provisions of the FD&C Act and the special controls identified in this order.

Unique device identification requirements apply broadly to all medical devices, unless an exception or alternative applies. Please note that because the UDI compliance dates are phased in over time based on device risk, and because the UDI regulations include some device class-specific provisions, this classification decision may impact your UDI implementation. For additional information, please visit our website at www.fda.gov/udi.

If you have any questions concerning this classification order, please contact David Hwang at (301) 796-3217.

Sincerely,

/s/

Angela C. Krueger
Associate Director
Regulation, Policy and Guidance
Office of Product Evaluation and Quality
Center for Devices and Radiological Health