July 6, 2020

RTI Surgical, Inc.
℅ Mr. Glenn Stiegman
Senior Vice President, Clinical and Regulatory Affairs
MCRA, LLC
1050 K Street NW, Suite 1000
Washington, District of Columbia 20001

Re: Q200824
Trade/Device Name: coflex Interlaminar Technology Instrumentation
Evaluation of Accessory Classification Under Section 513(f)(6) - Accessory Classification Request
Regulation Number: 21 CFR 888.4520
Regulation Name: Orthopedic manual surgical instrumentation for use with non-fusion spinous process spacer devices
Regulatory Classification: Class II
Product Code: QLR
Dated: April 15, 2020
Received: April 15, 2020

Dear Mr. 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 coflex Interlaminar Technology Instrumentation, prescription devices under 21 CFR 801.109 that are intended to manipulate tissue or implant materials for the positioning, alignment, placement, or removal of non-fusion spinous process spacer devices.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the coflex Interlaminar Technology Instrumentation, and substantially equivalent devices of this generic type, into Class II under the generic name Orthopedic manual surgical instrumentation for use with non-fusion spinous process spacer devices.

FDA identifies this generic type of device as:

Orthopedic manual surgical instrumentation for use with non-fusion spinous process spacer devices
Identification. Orthopedic manual surgical instruments for use with non-fusion spinous process spacer devices are non-powered hand-held devices designed specifically for use with non-fusion spinous process spacer devices and interface with the associated implant for the purpose of inserting,

positioning, or removing the implant. This type of device includes instruments specific to the geometry of the implant.

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 announcing the classification.

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 announcing the classification.

FDA received your Accessory Classification request on April 15, 2020 to classify the coflex Interlaminar Technology Instrumentation into Class II under section 513(f)(6)(D)(ii) of the FD&C Act. In order to classify the coflex Interlaminar Technology Instrumentation into Class I or 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 request and the information in the amended request provided via email on June 22, 2020, FDA has determined that the coflex Interlaminar Technology Instrumentation intended to manipulate tissue or implant materials for the positioning, alignment, placement, or removal of non-fusion spinous process spacer devices 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.

Identified Risks to Health	Mitigation Measures
Adverse tissue reaction	Biocompatibility evaluation
Infection	Reprocessing validation Sterilization validation Labeling
Implant damage or malpositioning	Validation of technical specifications Labeling

In combination with the general controls of the FD&C Act, Orthopedic manual surgical instrumentation for use with non-fusion spinous process spacer devices is subject to the following special controls:

(i) Technical specifications regarding geometry of the instruments must be specified and validated to demonstrate that the instruments can safely position, place, or remove the implant.
(ii) The patient contacting components of the device must be demonstrated to be biocompatible.
(iii) Performance data must demonstrate that reprocessing of reusable devices that are provided non-sterile, or sterilization of devices provided sterile, is validated.
(iv) Labeling must include:
  (A) Identification of implant(s) and instruments which have been validated for use together; and
  (B) Validated methods and instructions for reprocessing any reusable parts.

Section 510(m)(2) of the FD&C Act provides that FDA may exempt a Class II device from the premarket notification requirements under section 510(k) if, after notice of our intent to exempt and consideration of comments, we determine that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. We believe this may be such a device type, and a notice of intent to exempt the device type from premarket notification requirements may appear in the same issue of the **Federal Register** in which we announce this classification order.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

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, if applicable, 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 Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and is 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.

If you have any questions concerning this classification order, please contact Anne Talley, Ph.D. at 240-402-6536 or Anne.Talley@fda.hhs.gov.

Sincerely,

/s/

CAPT Raquel Peat, Ph.D., M.P.H., USPHS
Director
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health