DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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Augmenix, Inc. April 1, 2015
C/O Noel Rolon
Vice President, Clinical, Regulatory, and Quality
204 Second Ave., Lower Level
Waltham, MA 02451

Re: DEN140030
SpaceOAR System
Evaluation of Automatic Class III Designation – *De Novo* Request
Regulation Number: 21 CFR 892.5725
Regulation Name: Absorbable perirectal spacer
Regulatory Classification: Class II
Product Code: OVB
Dated: September 30, 2014
Received: October 01, 2014

Dear Noel Rolon:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your *de novo* request for classification of the SpaceOAR System, a prescription device under 21 CFR 801.109. The intended use of the SpaceOAR System is

> SpaceOAR System is intended to temporarily position the anterior rectal wall away from the prostate during radiotherapy for prostate cancer and in creating this space it is the intent of SpaceOAR System to reduce the radiation dose delivered to the anterior rectum. The SpaceOAR System is composed of biodegradable material and maintains space for the entire course of prostate radiotherapy treatment and is completely absorbed by the patient's body over time.

FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies the SpaceOAR System, and substantially equivalent devices of this generic type, into class II under the generic name, "Absorbable perirectal spacer."

FDA identifies this generic type of device as: Absorbable perirectal spacer.

An absorbable perirectal spacer is composed of biodegradable material that temporarily positions the anterior rectal wall away from the prostate during radiotherapy for prostate cancer with the intent to reduce the radiation dose delivered to the anterior rectum. The absorbable spacer maintains space for

the entire course of prostate radiotherapy treatment and is completely absorbed by the patient's body over time.

Section 513(f)(2) of the Food, Drug & Cosmetic Act (FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This new law provides two options for *de novo* classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the FD&C Act may, within 30 days of receiving notice of the NSE determination, request FDA to make a risk-based classification of the device under section 513(a)(1) of the FD&C Act. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the FD&C Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** classifying the device type.

On October 01, 2014, FDA received your *de novo* request for classification of the SpaceOAR System. The petition was submitted under section 513(f)(2) of the FD&C Act. In order to classify the SpaceOAR System into class I or II, it is necessary that the proposed class 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 *de novo* request, FDA has determined that the SpaceOAR System intended for use as follows

> SpaceOAR System is intended to temporarily position the anterior rectal wall away from the prostate during radiotherapy for prostate cancer and in creating this space it is the intent of SpaceOAR System to reduce the radiation dose delivered to the anterior rectum. The SpaceOAR System is composed of biodegradable material and maintains space for the entire course of prostate radiotherapy treatment and is completely absorbed by the patient's body over time.

can be classified in class II with the establishment of special controls for this type of device. FDA believes that the class II special controls identified later in this order, along with the applicable general controls, provide reasonable assurance of the safety and effectiveness of the device type.

Table – Identified Risks and Required Mitigations

Identified Risks	**Required Mitigations**
Device functional failure or the device is unable to maintain space stability during the course of radiation therapy	Special Controls (1)(i), (1)(ii), (1)(iv), and (1)(vi)
Prolonged or delayed procedure	Special Controls (1)(iii), (1)(iv), (2), and (3)

Needle penetration and/or spacer material injection into bloodstream, bladder, prostate, rectal wall, rectum or urethra	Special Controls (1)(iv), (2), and (3)
Incomplete absorption	Special Controls (1)(iii), (1)(iv), and (1)(vii)
Infection or local tissue inflammatory reactions	Special Controls (1)(iv), (1)(v), (1)(vi), (1)(vii), and (3)
Pain or discomfort associated with spacer	Special Controls (1)(iv) and (3)
Urine retention, bleeding, rectal mucosal damage, ulcers, necrosis, constipation, or rectal urgency	Special Controls (1)(iii), (1)(iv), (1)(vii), (2), and (3)

In combination with the general controls of the FD&C Act, an absorbable perirectal spacer is subject to the following special controls:

(1) The premarket notification submission must include methodology and results of the following non-clinical and clinical performance testing. For all clinical investigations used to support premarket notification submissions for this type of device, line listings of the study data must be provided.

(i) Performance bench testing must demonstrate appropriate perirectal space creation and maintenance for the duration of prostate radiotherapy;
(ii) Performance bench testing must demonstrate that therapeutic radiation levels do not alter the performance of the device;
(iii) Performance in vivo testing must demonstrate appropriate deployment of spacer as indicated in the accompanying labeling, and demonstrate appropriate expansion and absorption characteristics in a clinically relevant environment;
(iv) Clinical study must demonstrate appropriate spacer stability and lack of migration for the entire course of radiotherapy, complete absorption, and lack of long term toxicity;
(v) Sterility testing must demonstrate the sterility of the device and the effects of the sterilization process on the physical characteristics of the spacer;
(vi) Shelf-life testing must demonstrate the stability of the physical characteristics of the spacer throughout the shelf-life as indicated in the accompanying labeling; and,
(vii) The device must be demonstrated to be biocompatible.

(2) The risk management activities performed as part of the manufacturer's 21 CFR 820.30 design controls must document an appropriate end user initial training program which will be offered as part of efforts to mitigate the risk of failure to correctly operate the device, including, but not limited to, documentation of an

appropriate end user initial training program on the proper spacer deployment technique.

(3) The device labeling must include the following:
   (i) A detailed summary of reported or observed complications related to the use of the device;
   (ii) Appropriate warnings;
   (iii) Detailed instructions for system preparations and detailed implant procedure instructions; and,
   (iv) An expiration date that is supported by performance data as specified in subparagraph (b)(i)(vi).

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

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the absorbable perirectal spacer they intend to market prior to marketing the device and receive clearance to market from FDA.

Please be advised that FDA's decision to grant this *de novo* request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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); 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 and supporting documentation are 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 immediately market your device as described in the *de novo* request, subject to 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 Jin Zhang at 301-796-5938.

Sincerely yours,

Robert A Ochs

Robert Ochs, Ph.D.
Acting Director
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