DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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August 26, 2015

Artann Laboratories, Inc.
Noune Sarvazyan, Ph.D.
Chief Executive Officer
1459 Lower Ferry Road
Trenton, NJ 08618

Re: DEN100016
Prostate Mechanical Imager (PMI)
Evaluation of Automatic Class III Designation - *De Novo* Request
Regulation Number: 21 CFR 876.2050
Regulation Name: Prostate Lesion Documentation System
Regulatory Classification: Class II
Product Code: OQT
Dated: May 21, 2010
Received: May 21, 2010

Dear Dr. Sarvazyan:

This letter corrects our classification letter of April 27, 2012.

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your Evaluation of Automatic Class III Designation Petition (*de novo*) for classification of the Prostate Mechanical Imager (PMI), a prescription device under 21 CFR Part 801.109 that is indicated for:

> *the production of an elasticity image of the prostate as an aid in documenting prostate abnormalities that were previously identified by digital rectal examination (DRE). The device utilizes a transrectal probe with pressure sensor arrays and a motion tracking system and provides real-time elasticity images of the prostate. This device is limited to use as a documentation tool and therefore is not to be used for cancer diagnosis or for any other diagnostic purpose. This device is only to be used to image and document an abnormality that was already identified by DRE. Clinical management decisions are not to be made on the basis of information from the PMI device, but rather on the basis of the DRE. If there is disagreement between the DRE and the recorded image produced by the device, patient management decisions are to be based on the DRE and other available clinical and diagnostic information (e.g., prostate-specific antigen (PSA) levels) in accordance with standard medical practice.*

FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies the Prostate Mechanical Imager (PMI), and substantially equivalent devices of this generic type, into class II under the generic name, Prostate lesion documentation system.

FDA identifies this generic type of device as:

> **Prostate lesion documentation system**. A prostate lesion documentation system is a prescription device intended for use in producing an image of the prostate as an aid in documenting prostate abnormalities previously identified during a digital rectal examination. The device uses pressure sensors and image reconstruction software to produce a prostate image that highlights regional differences in intraprostatic tissue elasticity or stiffness. The device is limited to use as a documentation tool and is not intended for diagnostic purposes or for influencing any clinical decisions.

Section 513(f)(2) of the 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 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 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 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.

In accordance with section 513(f)(1) of the FD&C Act, FDA issued an order on April 22, 2010, automatically classifying the Prostate Mechanical Imager in class III, because it was not within a type of device which was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, nor which was subsequently reclassified into class I or class II. On May 21, 2010, FDA received your *de novo* requesting classification of the Prostate Mechanical Imager into class II. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Prostate Mechanical Imager 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 Prostate Mechanical Imager indicated for

> *the production of an elasticity image of the prostate as an aid in documenting prostate abnormalities that were previously identified by digital rectal examination (DRE). The device utilizes a transrectal probe with pressure sensor arrays and a motion tracking system and provides real-time elasticity images of the prostate. This device is limited to use as a documentation tool and therefore is not to be used for cancer diagnosis or for any other diagnostic purpose. This device is only to be used to image and document an abnormality that was already identified by DRE. Clinical management decisions are not to be made on the basis of information from the PMI device, but rather on the basis of the DRE. If there is disagreement*

between the DRE and the recorded image produced by the device, patient management decisions are to be based on the DRE and other available clinical and diagnostic information (e.g., prostate-specific antigen (PSA) levels) in accordance with standard medical practice

can be classified in class II with the establishment of special controls for class II. FDA believes 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	**Mitigation Measure**
Failure to consistently produce an accurate image	Performance Testing (non-clinical and clinical) Software Verification, Validation, and Hazard Analysis Labeling
Misinterpretation of displayed images	Labeling
User error	Labeling
Microbial contamination from reusable components	Labeling Validation of Reprocessing Methods and Instructions
Adverse tissue reaction	Biocompatibility Testing
Electromagnetic incompatibility	Electromagnetic Compatibility Testing
Electrical injury	Electrical Safety Testing
Thermal injury	Thermal Safety Testing
Mechanical injury	Mechanical Safety Testing

In combination with the general controls of the FD&C Act, the Prostate lesion documentation system is subject to the following special controls:

(1) Non-clinical and clinical performance testing must demonstrate the accuracy and reproducibility of the constructed image.
(2) Appropriate analysis/testing must validate electromagnetic compatibility (EMC), electrical safety, thermal safety, and mechanical safety.

(3) Appropriate software verification, validation, and hazard analysis must be performed;

(4) All elements of the device that may contact the patient must be demonstrated to be biocompatible.

(5) Methods and instructions for reprocessing of any reusable components must be properly validated.

(6) The labeling must include specific information needed to ensure proper use of the device.

In addition, this is a prescription device and must comply with 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, this device type 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 Prostate lesion documentation system they intend to market and receive clearance to market from FDA prior to marketing the device.

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 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); 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 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 Mr. Robert De Luca at (301) 796-6551.

Sincerely,

Jonette R. Foy -S

Jonette Foy, Ph.D.
Deputy Director
for Science and Regulatory Policy
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