FUJIFILM Corporation  
% Mr. Jeffrey Wan  
Specialist, Regulatory Affairs  
FUJIFILM Medical Systems U.S.A., Inc.  
81 Hartwell Avenue, Suite 300  
LEXINGTON MA  02421

Re: K191495  
Trade/Device Name: Biopsy Positioner (FDR -2000BPY)  
Regulation Number: 21 CFR 892.1710  
Regulation Name: Mammographic x-ray system  
Regulatory Class: Class II  
Product Code: IZH  
Dated: May 31, 2019  
Received: June 5, 2019

Dear Mr. Wan:

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](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](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.


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](https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance)) and CDRH Learn ([https://www.fda.gov/training-and-continuing-education/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](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,

[Signature]

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure
Indications for Use

The FUJIFILM Biopsy Positioner (FDR-2000BPY) is an optional accessory for the Aspire Cristalle (FDR MS-3500) digital mammography system. It is designed to allow for accurate determination of three dimensional lesion locations in the breast using information extracted from stereotactic pairs of two-dimensional images and/or Digital Breast Tomosynthesis (DBT) images. It is intended to provide guidance for interventional purposes (such as biopsy, pre-surgical localization or treatment devices).

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.

"DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW."

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Date Prepared: July 3, 2019

Submitter's Information:
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Ashigarakami-Gun, Kanagawa, 258-8538, Japan
FDA Establishment Registration Number: 3001722928

Contact Person:
Jeffrey Wan
Specialist, Regulatory Affairs
Telephone: (201) 675-8947
Email: jeffrey.wan@fujifilm.com

Device Name and Classification:
Product Name: Biopsy Positioner
Model Number: FDR-2000BPY
Classification Name: Mammographic X-ray system
Classification Panel: Radiology
CFR Section: 21 CFR 892.1710
Device Class: Class II
Product Code: IZH

Predicate Devices:

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Primary Predicate</th>
<th>Reference Predicate</th>
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<tbody>
<tr>
<td>FUJIFILM Biopsy Positioner (FDR-1000BPY)</td>
<td>Affirm Breast Biopsy Guidance System</td>
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<tr>
<td>K113284</td>
<td>K122836</td>
<td></td>
</tr>
<tr>
<td>Mammographic X-ray system</td>
<td>Mammographic X-ray system</td>
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<td>Radiology</td>
<td>Radiology</td>
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<tr>
<td>21 CFR 892.1710</td>
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**Indications for Use:**

The FUJIFILM Biopsy Positioner (FDR-2000BPY) is an optional accessory for the Aspire Cristalle (FDR MS-3500) digital mammography system. It is designed to allow for accurate determination of three dimensional lesion locations in the breast using information extracted from stereotactic pairs of two-dimensional images and/or Digital Breast Tomosynthesis (DBT) images. It is intended to provide guidance for interventional purposes (such as biopsy, pre-surgical localization or treatment devices).

**Description of the Device:**

The Biopsy Positioner (FDR-2000BPY) is an optional accessory for the Digital Mammography system. It is designed for positioning the needle when performing Stereotactic and/or Tomosynthesis Biopsies, fine needle aspirations, core needle, and vacuum assisted biopsies in an upright position. The Biopsy Positioner uses a Stereo pair of images and/or Tomosynthesis images. The position of the three coordinates (X, Y, and Z) is computed using the position of the object on each of the images, as indicated by the operator, and the known geometry of the system.

FDR-2000BPY is mainly composed of the following elements:

- The Positioner that supports and positions the needle
- The Positioner Control Cabinet which supplies power to the positioned
- The Operation panel which displays the distance between the compression plate and target pathology, the distance between the target pathology and the needle, and also electrically drives the positioner in the X, Y and Z directions.

The subject of this Special 510(k) premarket notification is adding use of Digital Breast Tomosynthesis (DBT) images for extracting information to determine three dimensional lesion locations in the breast.

**Comparison of Technological Characteristics:**

The Biopsy Positioner (FDR-2000BPY) differs from the predicate device in the following modifications:

- Addition of tomosynthesis biopsy feature
- Compatibility with additional needle guides

A comparison of the technological characteristics between the proposed device and predicate devices is provided below:
### Biopsy Positioner (FDR-2000BPY)
- **K number**: K191495
- **IFU**: The FUJIFILM Biopsy Positioner (FDR-2000BPY) is an optional accessory for the Aspire Cristalle (FDR MS-3500) digital mammography system. It is designed to allow for accurate determination of three dimensional lesion locations in the breast using information extracted from stereotactic pairs of two-dimensional images and/or Digital Breast Tomosynthesis (DBT) images. It is intended to provide guidance for interventional purposes (such as biopsy, pre-surgical localization or treatment devices).
- **Type of biopsy system**: Same as K122836
- **Exposure position**: Same as K122836 ±15° (Stereo Exposure) ±15° (Stereo Exposure) ±7.5° (Tomosynthesis Exposure)
- **Positioning accuracy**: ±1mm
- **Weight**: Biopsy Unit 5.5kg 7.0kg
- **Positioning method**: Electrically & Manually
- **Method of beam limitation**: Automatic collimation
- **Size of biopsy Field of View**: 6.0cm x 7.0cm 5.4cm x 5.2cm 7.4cm x 6.2cm
- **Lateral Approach**: Yes

### Biopsy Positioner (FDR-1000BPY)
- **K number**: K113284
- **IFU**: The FUJIFILM Biopsy Positioner (FDR-1000BPY) is an optional accessory for the Aspire HD (FDR MS-1000) digital mammography system. It is designed to allow for accurate determination of three dimensional lesion locations in the breast using information extracted from stereotactic pairs of two-dimensional images. It is intended to provide guidance for interventional purposes (such as biopsy, pre-surgical localization or treatment devices).
- **Type of biopsy system**: Stereo Biopsy
- **Exposure position**: ±15°(Stereo Exposure)
- **Positioning accuracy**: ±1mm
- **Weight**: Biopsy Unit 5.5kg
- **Positioning method**: Electrically & Manually
- **Method of beam limitation**: Automatic collimation
- **Size of biopsy Field of View**: 6.0cm x 7.0cm
- **Lateral Approach**: Yes

### Affirm Breast Biopsy Guidance System
- **K number**: K122836
- **IFU**: The Affirm Breast Biopsy Guidance System is an optional accessory for the Selenia Dimensions Mammography System. It is designed to allow the accurate localization of lesions in the breast in three dimensions. It is intended to provide guidance for interventional purposes (such as biopsy, pre-surgical localization or treatment devices).
- **Type of biopsy system**: Stereo Biopsy Tomosynthesis Biopsy
- **Exposure position**: ±15°(Stereo Exposure) ±7.5°(Tomosynthesis Exposure)
- **Positioning accuracy**: ±1mm
- **Weight**: Biopsy Unit 5.5kg 7.0kg
- **Positioning method**: Electrically & Manually
- **Method of beam limitation**: Automatic collimation
- **Size of biopsy Field of View**: 6.0cm x 7.0cm 5.4cm x 5.2cm 7.4cm x 6.2cm
- **Lateral Approach**: Yes
<table>
<thead>
<tr>
<th><strong>Compression system</strong></th>
<th>Biopsy Positioner (FDR-2000BPY)</th>
<th>Biopsy Positioner (FDR-1000BPY)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Construction material / type of biopsy compression paddle</td>
<td>Same as K113284</td>
<td>Plastic</td>
</tr>
</tbody>
</table>
| Lockout movement when under compression | Same as K113284 | All movements shall be inhibited when:  
  - The compression force is detected to be more than 30N  
  - The needle is attached to the needle holder |
| Automatic detection of biopsy unit | Same as K113284 | Yes (alarm sounds and warning displayed on indication panel if not connected properly) |

<table>
<thead>
<tr>
<th><strong>Needle Guide</strong></th>
<th>Needle guide positioning</th>
<th>Same as K113284</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positioning software</td>
<td>Same as K113284</td>
<td>Fujifilm</td>
<td></td>
</tr>
<tr>
<td>Calibration frequency</td>
<td>Same as K113284</td>
<td>User executes the accuracy testing at every use and an annual maintenance check is performed</td>
<td></td>
</tr>
<tr>
<td>Mammotome-compatible Devicor Medical Products</td>
<td>Same as K113284</td>
<td>Yes</td>
<td></td>
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<table>
<thead>
<tr>
<th><strong>Mammotome Compatible</strong></th>
<th>Yes</th>
<th>No</th>
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<tbody>
<tr>
<td>Hologic ATEC/Eviva</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>BARD Compatible</td>
<td>Same as K113284</td>
<td>Yes</td>
</tr>
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</table>

**Performance Data:**

Biopsy Positioner (FDR-2000BPY) was evaluated for electromagnetic compatibility and radiation safety when used with the Aspire Cristalle (FDR MS-3500) digital mammography system in accordance with IEC 60601-1-2:2014, IEC 60601-1-3:2013, and IEC 60601-2-45:2015. The proposed device met all acceptance criteria described in these standards.

Software validation was evaluated in accordance with ANSI/AAMI/IEC 62304:2006 and the FDA guidance, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices”.

Bench testing was performed on the Biopsy Positioner (FDR-2000BPY) to evaluate the stereotactic and tomosynthesis biopsy needle positioning accuracy when used with the Aspire Cristalle (FDR MS-3500) digital mammography system.
**Substantial Equivalence**

The modified FUJIFILM Biopsy Positioner (FDR-2000BPY) is adding the intended use with Digital Breast Tomosynthesis (DBT) images for extracting information to determine three dimensional lesion locations in the breast. Both the modified and primary predicate devices have the same fundamental scientific technology, principles of operation, performance, and design and materials. The addition of the tomosynthesis biopsy feature is supported by the reference predicate device. Therefore, FDR-2000BPY can be considered to be substantially equivalent to FDR-1000BPY.

**Conclusion:**

This Special 510(k) premarket notification submission has demonstrated Substantial Equivalence as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health. We conclude the subject device to be as safe and effective as the predicate device.