



Food and Drug Administration  
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Women's Imaging Solutions Enterprises, LLC  
Erika Huffman  
Prin. Medical Research Manager  
4050 OLSON MEMORIAL HIGHWAY  
MINNEAPOLIS MN 55422

December 22, 2015

Re: K152038  
Trade/Device Name: MammoGRIP  
Regulation Number: 21 CFR 892.1710  
Regulation Name: Mammographic X-Ray System (accessory)  
Regulatory Class: II  
Product Code: IZH  
Dated: December 14, 2015  
Received: December 16, 2015

Dear Ms. Huffman:

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. 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); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink that reads "Robert Ochs". The signature is written in a cursive style with a light grey shadow effect behind the text.

Robert Ochs, Ph.D.  
Director  
Division of Radiological Health  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K152038

Device Name

MammoGRIP

Indications for Use (Describe)

MammoGRIP aids in positioning during radiologic visualization of the breast.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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## 6.0 510(k) Summary

<b>Submitter:</b>	MammoGRIP LLC
<b>Contact Person:</b>	Erika Huffman Medical Research Manager, Regulatory NAMSA 4050 Olson Memorial Hwy. Suite 450 Minneapolis, MN 55422 Phone: +1-763-588-9857 Fax: +1-763-287-3836 <a href="mailto:ehuffman@namsa.com">ehuffman@namsa.com</a>
<b>Date Prepared:</b>	July 17, 2015
<b>Trade Name:</b>	MammoGRIP™
<b>Common Name:</b>	Mammography positioning aid
<b>Classification Name:</b>	Accessory to X-Ray Mammographic System, 21 CFR Part 892.1710
<b>Regulatory Class:</b>	Class II
<b>Product Code:</b>	IZH
<b>Predicate Device:</b>	K062141-MammoPad Radiolucent Cushion <i>This predicate device has not been subject to a design-related recall.</i>
<b>Device Description:</b>	MammoGRIP™ is a non-medicated, 0.1% benzalkonium chloride foam solution intended to be used during mammography to facilitate breast positioning. When MammoGRIP is applied to the technician's hands, it imparts a slightly tacky or sticky surface while it is still damp, thereby allowing the technician to have a better grip of the dry breast tissue for optimal positioning in the field of view of the mammography machine. MammoGRIP is intended to be used with standard mammogram positioning techniques.
<b>Indications for Use:</b>	MammoGRIP aids in positioning during radiologic visualization of the breast.
<b>Comparison of the Technological Characteristics with the Predicate Device:</b>	The MammoGRIP device is similar to the MammoPad device in the following ways: <ul style="list-style-type: none"> <li>• Each of the devices is intended to be used as an aid to positioning during radiologic visualization of the breast.</li> <li>• Each of the devices is radiolucent.</li> <li>• Each of the devices is provided non-sterile.</li> </ul>

	<p>The MammoGRIP device is different from the predicate device in the following ways:</p> <ul style="list-style-type: none"> <li>• Physical Form</li> </ul>
<b>Performance Data:</b>	<p>The MammoGRIP device meets the following biocompatibility standards:</p> <ul style="list-style-type: none"> <li>• Intracutaneous Injection Test (Irritation) per ISO 10993-10</li> <li>• Kligman Maximization Test (Sensitivity) per ISO 10993-10</li> </ul> <p>The following characteristics are verified for each lot: pH, appearance, odor, and benzylkonium chloride content. In addition, radiolucency of the MammoGRIP device has been demonstrated.</p>
<b>Conclusion:</b>	<p>The data provided in this submission support the safety of the MammoGRIP device and demonstrate that the MammoGRIP device is substantially equivalent to the predicate device which is currently marketed for the same intended use.</p>