ADANI
% Daniel Kamm, P.E.
Principal Engineer
Kamm & Associates
8870 Ravello Ct.
NAPLES FL 34114

October 20, 2017

Re: K172027
Trade/Device Name: Adani MammoScan
Regulation Number: 21 CFR 892.1715
Regulation Name: Full-field digital mammography system
Regulatory Class: II
Product Code: MUE
Dated: September 18, 2017
Received: September 21, 2017

Dear Mr. Kamm:

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 (DICE) 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 (DICE) 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,

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K17 2027

Device Name
Adani MammoScan

Indications for Use *(Describe)*
The MammoScan® Full-Field Digital Mammography System is a device intended to produce planar digital x-ray images of the entire breast. The MammoScan is indicated for generating mammographic images that can be used for screening and diagnosis of breast cancer. The MammoScan is intended to be used in the same clinical applications as traditional film/screen systems.

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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510(k) Summary K17

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Contact: Vladimir Klokov, Vice President
Date Prepared: June 4, 2017

1. Identification of the Device:
   Proprietary-Trade Name: Adani MammoScan®
   Classification Name: Full-Field Digital Mammography System
   Product Code: MUE
   Regulation 892.1715
   Common/Usual Name: Digital Mammography System.

2. Equivalent legally marketed device: P010017, SenoScan® Full-Field Digital Mammography System, Fischer Imaging Corporation Denver, CO 80026.
   Classification Name: Full-Field Digital Mammography System
   Product Code: MUE
   Regulation 892.1715
   Common/Usual Name: Digital Mammography System.

3. Indications for Use (intended use): The MammoScan® Full-Field Digital Mammography System is a device intended to produce planar digital x-ray images of the entire breast. The MammoScan is indicated for generating mammographic images that can be used for screening and diagnosis of breast cancer. The MammoScan is intended to be used in the same clinical applications as traditional film/screen systems.

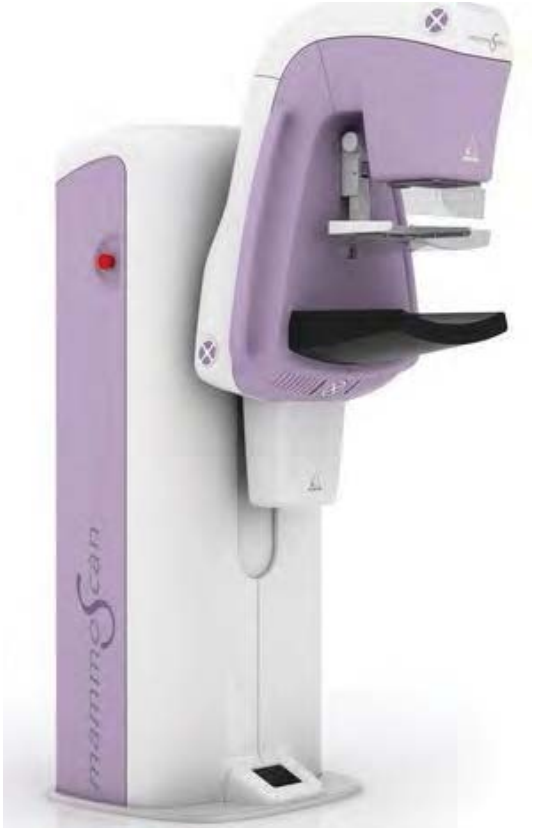
4. Description of the Device: The Adani MammoScan is a full-field type digital mammography system comprised of an image acquisition system, a gantry and an acquisition station, equipped with PC computer, keyboard, mouse, monitor and a protective shield. The image acquisition system includes a built-in digital detector of CCD-TDI technology, x-ray tube (with tungsten target and aluminum filtration), high voltage generator, compression mechanism, and slit collimator. The slit-collimator shapes the beam and limits the x-ray beam to the active width of the detector, which prevents image degradation caused by scattered radiation. During image acquisition, the internal swing arm is motor driven to pivot at the x-ray tube with the slit collimator, causing the detector (at the other end of the swing arm and on the far side of the breast support) to swing in an arc under the breast support from one edge of the breast support to the other. The x-ray, which is shaped into a flat fan-shaped beam by the slit collimator, passes through the compressed breast tissue as it sweeps across the breast support and falls on the image detector underneath. The acquisition workstation is the user interface for preparing and initiating image acquisition, image pre- and post-processing, and image transfer to the desired destination (e.g. PACS) for interpretation and archiving. The MammoScan® Full-Field Digital Mammography System consists of a high-voltage generator, gantry, an acquisition work station with a technologist shield and accessories. The patient is imaged at the gantry. The gantry contains the diagnostic source (x-ray tube, filter, and collimator), built-in solid state image detector, breast support, and compression assembly. The gantry can be raised, lowered, and rotated, under motorized control, to accommodate patients of all statures, standing and/or sitting, to produce images in all standard views.

5. Safety and Effectiveness, comparison to predicate device. The Adani MammoScan system employs the same fundamental technological characteristics as its predicate device and The X-ray technology is substantially equivalent to the Fischer SenoScan Full Field Digital Mammography System, approved by FDA via P010017. Clinical uses for which Adani MammoScan was designed are equivalent to those cleared for Fischer SenoScan.

The Adani MammoScan and Fischer SenoScan use same technology for converting x-rays to the electric signal. The results of bench, clinical, and standards testing indicates that the new device is as safe and effective as the predicate device. Risk analysis and software validation has been performed. An examination of the substantial equivalence chart below reveals the use of nearly identical or equivalent technology throughout.

6. Substantial Equivalence Chart, MammoScan® vs. Predicate

Parameter	**Predicate device, SenoScan® , P010017**	**New device, MammoScan®, this submission**
Indications	The SenoScan® Full-Field Digital Mammography System is a dedicated mammography system intended to produce radiographic images of the human breast for the purpose of diagnostic and screening mammography. The SenoScan® Full-Field Digital Mammography system is intended to be used in the same clinical applications as traditional film-based mammographic systems	The MammoScan® Full-Field Digital Mammography System is a device intended to produce planar digital x-ray images of the entire breast. The MammoScan is indicated for generating mammographic images that can be used for screening and diagnosis of breast cancer. The MammoScan is intended to be used in the same clinical applications as traditional film/screen systems.
Detector Information		
Type	Cesium iodide with 4 TDI CCD's	Cesium iodide with 2 TDI CCD's
Detector area	21x1 cm	22x0.7 cm
Maximum field size	22x30 cm	22x30 cm
Pixel dimensions	Native pixel size 27 µm 54 µm in normal operation mode	Native pixel size 27 µm 54 µm in normal operation mode
Fill factor	100 %	100 %
Matrix size	4096x5625 pixels	4096x5560 pixels
X-Ray interaction material	CsI:Tl	CsI:Tl
A/D conversion bit depth	12 bits	16 bits
Scanning rate	-	4.6 Cm/sec
Decay rate of the phosphor afterglow	less than 3 µs	less than 3 µs
Image read-out mechanism.	CCD TDI	CCD TDI
Method of detector cooling	Air/Fan	Air/Fan
Power source	220 VAC	220 VAC
X-Ray Parameters:		
X-Ray tube model name	Varian RAD73	Varian RAD70 or IAE XM 1016T
Focal Spot Size	0.3 mm	0.3 mm
Inherent filtration	0.76 mm Be	0.76 mm Be or 0.5 mm Be
Target material	Rhenium-tungsten facing on molybdenum	Rhenium-tungsten
Heat capacity	600 kHU	600 kHU or300 kHU

Parameter	**Predicate device, SenoScan® , P010017**	**New device, MammoScan®, this submission**
Additional Equivalent Filtration in X-ray Beam	0,5 mm Al in normal operation 2,0 mm Al for calibration – automatically selected	0,5 mm Al in normal operation 2,0 mm Al for calibration – automatically selected
Collimator operation	Fixed at front and sides, motorized rear blade	Fixed at front and sides, motorized rear blade
Projected X-Ray beam	1x22cm	0,7x22 cm
Generator Information		
Type	High frequency	High frequency, Model name : Sedecal SHF-1030-M
Maximum power	12 kW	10 kW
Output voltage range	20-45 kV with 1 kV step maximum ripple 3%	20-50 kV with 0.1 kV step maximum ripple 1%
Output current range	80-200 mA	5-250 mA, From 5 mA to 80 mA in 0.1 mA steps and from 80 mA to 250 mA in 1 mA steps
Output mAs range	-	0.1 to 1200 mAs
Operation of AEC	-	AEC is implemented using pre-scan (not on generator level)
Backup timer:	Yes	Yes
Photo		

7. Description of non-clinical (bench) testing: The device has been evaluated for as electrical, electromagnetic, radiation, and mechanical safety, and has been found to conform to the following medical device safety standards:

EN 60601-1:2006/ A1:2013 General Requirements for Safety
EN 60601-1-2:2007/ A:2010 EMC Electromagnetic compatibility-Requirements and tests
EN 60601-1-3:2008/ A:2010 Collateral Standard: Radiation protection in diagnostic X-ray equipment
EN 60601-1-6:2010/ A1:2015 Collateral Standard: Usability
IEC 60601-2-45:2011 Particular requirements for the safety of mammographic X-ray equipment and mammographic stereotactic devices
EN ISO 15223-1:2012 Symbols to be used with medical device labels, labeling and information to be supplied
EN ISO 14971:2012 - Application of risk management to medical devices
EN 62220-1-2:2010 Determination of the detective quantum efficiency - Detectors used in mammography
EN 62304:2006 + AMD1:2015 CSV Medical device software - Software life-cycle processes
EN 62366:2008/ A1:2015 Medical devices – Application of usability engineering to medical devices
EN 1041:2008/ A1:2013 Information supplied by the manufacturer of medical devices
EN ISO 14155:2011 Clinical investigation of medical devices for human subjects – Good clinical practice

Performance data from non-clinical testing of the Adani MammoScan covering Sensitometric response, Spatial resolution, Noise analysis, Signal-to-noise-ratio transfer - DQE, Dynamic range, Automatic exposure control performance, Phantom testing, Patient radiation dose, and Image erasure, fading and repeated exposure was compared with data from the PMA Summary of Safety and effectiveness of the predicate device. This comparison showed that the Adani MammoScan device performed as well as or better than the predicate devices in all relevant areas.

Biocompatibility testing according to ISO 10993 was performed for the patient contact material, the compression plate: cytotoxicity, irritation, sensitization.

8. SUMMARY OF THE CLINICAL IMAGE ATTRIBUTE EVALUATION
An image attribute evaluation was conducted in accordance with the Guidance for Industry and FDA Staff, Class II Special Controls Guidance Document: Full-Field Digital Mammography System [issued: March 27, 2012] which concluded that the images were of sufficiently acceptable quality for clinical mammographic usage.

9. SAFETY INFORMATION
The Adani MammoScan system introduces no new safety or efficacy issues other than those already identified with the predicate device. The results of the Risk analysis combined with the appropriate preventive measures taken indicate that the device is of moderate concern as per the May 11, 2005 issue of the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" and is consistent with the level of concern indicated in the "Class II Special Controls Guidance Document: Full-Field Digital Mammography System" document issued on: March 27, 2012.

10. Conclusion: The Adani MammoScan described in this submission is substantially equivalent to the predicate device in respects of indication for use and image quality. The proposed and predicate devices utilize similar technology and materials, comparable safety and effectiveness features, and are similar in design and construction. The information submitted in this application shows that none of the technical differences between the systems raises new questions of safety and effectiveness. All collected performance data demonstrate that the devices are substantially equivalent. Our conclusion is that Adani MammoScan is as safe and effective as the legally marketed predicate device. After analyzing bench, clinical, risk analysis, software validation and standards testing data, it is the conclusion of Adani that the MammoScan® Full Field Digital Mammography System is as safe and effective as the predicate device, has no significant technological differences, and has no new indications for use, thus rendering it substantially equivalent to the predicate device.