K130779

510(k) Summary of Safety & Effectiveness

Pursuant to CFR 807.92, the following 510(k) Summary is provided:

1. (a)	**Submitter Address:**	George J. Hattub MedicSense, USA 291 Hillside Avenue Somerset, MA 02726 www.medicsense.com
1. (b)	***Manufacturer Address:***	DiACardio, Ltd. Meytag High-Tech Ventures P.O. Box 12, Katzrin, Israel 12900
	Mfg. Phone:	Tel.: +972 77 7648318
	Contact Person:	Mrs. Michal Yaacobi
	Date:	May 5, 2013
2.	***Device & Classification Name:***	Picture Archiving Device- classified as Class 2 LLZ, Regulation Number 21 CFR 892.2050 *LVivo EF* Software Application
3.	***Predicate Devices:***	K072090- Siemens Medical Solution SYNGO Auto Left Heart and VVL Clinical Feature K070792- Philips Ultrasound, Inc. QLAB 2D Cardiac Quantification Plug-In
4.	***Description:***	The LVivoEF System analyzes echocardiographic patient examination DICOM movies for Global ejection fraction (EF) evaluation. EF is evaluated using two orthogonal planes, four-chamber (4CH) and two-chamber (2CH) views, to provide fully automated analyses of LV function from the echo examination movies.
5.	***Intended Use:***	DiaCardio's *LVivo EF* Software Application is intended for non-invasive processing of already acquired echocardiographic images in order to detect, measure, and calculate the left ventricular wall for left ventricular function evaluation. This measurement can be used to assist the clinician in a cardiac evaluation.
6.	***Comparison of Technological Characteristics:***	With respect to technology and intended use, DiaCardio's *LVivo EF* Software Application is substantially equivalent to its predicate devices. Based upon the outcomes from clinical trials, DiaCardio believes that their device does not raise additional safety of efficacy concerns.
7.	***Clinical Tests:***	In this study, the performance of LVivoEF was compared with conventional

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methods used for LV function evaluation in echocardiography, including manual evaluation by sonographers and visual estimation by physicians. In the blinded clinical trial, ultrasound clips of 83 subjects were evaluated with the LVivoEF System. Average values were calculated for each variable measured by Manual Biplane Method (MBP) and Pearson correlation coefficients were calculated between MBP and LVivoEF results. The primary end point defined for this study was met with a correlation coefficient calculated for biplane EF ($r=0.88$, $p<0001$).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

DiaCardio, Ltd
c/o George Hattub
MedicSense, USA
291 Hillside Ave.
SOMERSET, MA 02726

August 15, 2013

Re: K130779
Trade/Device Name: LVivo EF Software Application
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: July 9, 2013
Received: July 17, 2013

Dear Mr. Hattub:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Michael D. O'Hara for

Janine M. Morris
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): K130779

Device Name: LVivo EF Software Application

Indications for Use:

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Prescription Use ___X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

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