JAN 11 2013

Special 510(k) (accessory to device)
Silicon Valley Medical Instruments, Inc.
510(k) Summary

Silicon Valley Medical Instruments Inc.™

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92

Submitter Information	
Name:	Silicon Valley Medical Instruments, Inc.
Address	47697 Westinghouse Drive, Suite 101, Fremont, CA 94539-7401 USA
Phone Number:	510-897-4695
Fax Number	510-226-1230
Establishment Registration Number	N/A – Not yet registered.
Contact Person	Richard E. Anderson; VP, RA/QA (richarda@svmii.com)
Date Prepared	07 September 2012

Name of Device	
Trade or Proprietary Name	HD-IVUS Ultrasound Imaging System
Common or Usual Name	System, Imaging, System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Classification Name	Class II
Classification Panel	Cardiovascular
Regulation	21 CFR 892.1560 (IYO)
Product Code(s)	IYO
Legally Marketed Device(s) to which Equivalence is Claimed	Boston Scientific Corporation's iLab Ultrasound Imaging System (Cleared 14Jul05 via K051679)
Reason for Submission	New device
Device Description	The HD-IVUS Ultrasound Imaging System is a minimally invasive intravascular ultrasound diagnostic imaging tool when used in conjunction with an intravascular ultrasound catheter. The System is a medical device for use by or on the order of a physician. The HD-IVUS Ultrasound Imaging System is comprised of a System Console with a touch screen monitor, a Roll Stand, or bed-rail swing arm mount, a Patient Interface Module (PIM), a Power Supply, and an Intravascular Ultrasound Catheter (510(k) cleared and sold separately). The Catheter emits sound energy from a transducer at the distal tip of the catheter, which is guided into the coronary arteries of the heart. Sound waves that reflect from the inner vascular tissues are received by the transducer and sent to the System Console where a high resolution, cross-sectional image is displayed in real time. The technique provides for in-vivo visualization of the coronary artery lumen, coronary artery wall morphology, and devices (such as stents) at or near the surface of

	the coronary artery wall. • **System Console** The HD-IVUS system features a point-of-care system console that is mounted to a roll stand, or bed-rail swing arm mount. The System Console is the central component that is responsible for: • managing the generation and display of IVUS images • storing and exporting the image data • providing the main user interface • providing analysis tools (i.e., area measurements, linear measurements, and annotations) The System Console receives, processes, displays, and records ultrasound image data from the transducer in the Kodama HD-IVUS catheter. The IVUS images are displayed on a high-resolution, 19-inch, flat panel, touch screen monitor. The monitor serves as the graphical user interface (GUI) for operating the system. All system information and controls are located on the touch screen monitor. The HD-IVUS system has internal storage for patient studies. Each study can contain data in the form of loops or stills. Study data is saved in DICOM format and can be exported to DVD, using the integrated DVD drive, or to a USB storage device, using one of the four USB ports. • **Roll Stand** The variable height roll stand supports the System Console and enables the console to be attached to a mobile stand that can be rolled up to the patient bed. • **Bed Rail Swing Arm** The bed rail swing arm mount supports the System Console and enables the console to be attached to a patient bed rail. • **Patient Interface Module (PIM)** The Patient Interface Module (PIM) provides the electromechanical interface between the catheter and the System Console. The PIM provides the mechanical interface to secure the catheter, as well as the mechanical energy to rotate the catheter's imaging assembly.

	The PIM also provides the electrical interface that transmits the signal from the integrated ultrasound generator to the catheter and receives the return signals. The PIM is placed into a sterile bag for normal use and can be situated near the patient in the sterile field. The PIM features an imaging on/off button and a recording on/off button. These controls enable the sterile operator to start or stop imaging and recording from within the sterile field. A LED light on the PIM indicates active recording. • **Linear Translation System (LTS) (subject of this submission)** The Linear Translation System (LTS) is an accessory (companion product) to the HD-IVUS system and provides for linear translation (pullback) of the catheter imaging element under motorized (controlled speed) linear translation when used in conjunction with the PIM. The LTS is an optional accessory and not required for basic IVUS imaging. • **Power Supply** The system includes a universal, medical grade external AC to DC power supply that enables direct connection to the hospital power source. • **Intravascular Ultrasound Catheter (510(k) cleared under K113008 and sold separately)** The Kodama Intravascular Ultrasound Catheter is a minimally invasive intravascular ultrasound coronary imaging catheter. The catheter emits acoustic energy from a transducer at its distal tip, which is guided into the coronary arteries of the heart. Sound waves that are reflected from vascular tissues are received by the transducer and sent through the PIM to the system console. The catheter can be operated at two different frequencies, 40 MHz or 60 MHz, depending on user preference. An integrated telescope allows the imaging of multiple regions of interest in a single procedure by advancing or retracting the imaging assembly without moving the catheter sheath. (NOTE: *Refer to the Directions for Use supplied with the Kodama Intravascular Ultrasound Catheter for additional information.)*
Intended Use of the Device	The HD-IVUS Ultrasound Imaging System (Console) is intended for ultrasound examination of coronary intravascular pathology only.

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Indications for Use	The HD-IVUS Ultrasound Imaging System (Console) is intended for ultrasound examination of coronary intravascular pathology only. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal coronary interventional procedures.

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Summary of the Technological Characteristics of the Device Compared to the Predicate Device		
Characteristic	**Predicate Device (SVMI's** HD-IVUS Ultrasound Imaging System – Cleared 17Dec11 via K112997)	**Additional Predicate** (Boston Scientific Corporation's iLab Ultrasound Imaging System – Cleared 14Jul05 via K051679)
Signal Type	Echo	Doppler, Echo
Catheter Mechanical Drive	Patient Interface Module (PIM) (cleared with ultrasound system)	Motor Drive Unit (MDU) (cleared with ultrasound system)
Linear Translation System (accessory to device(s))	**Subject of this submission – Linear Translation System** that allows for motorized (controlled speed) linear pullback (translation) of the catheter when used in conjunction with the PIM (above)	Pullback Sled that allows for linear pullback (translation) of the catheter when used in conjunction with the MDU (above)
Signal Conductor	Coaxial wire traveling down catheter	Coaxial wire traveling down catheter
Signal Generator/ Receiver Materials	PZT crystal transducer	PZT crystal transducer
Acoustic Output	Does not exceed Track 3 limits	Does not exceed Track 3 limits
Ultrasound Frequency	40 MHz, 60 MHz ± 10%	10-40 MHz ± 10%
Method of Use	Intravascular	Intravascular
User Interface	PC-based system with keyboard and touch screen and mouse	PC-based system with keyboard and touch screen and mouse
Software Interface	Custom GUI	Custom GUI
Intended Use	The HD-IVUS Ultrasound Imaging System (Console) is intended for ultrasound examination of coronary intravascular pathology only. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal coronary interventional procedures.	The iLab Ultrasound Imaging System is intended for ultrasound examinations of intravascular pathology. Intravascular ultrasound is indicated in patients who are candidates for transluminal interventional procedures such as angioplasty and atherectomy.

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Silicon Valley Medical Instruments Inc.™

Performance Data		
Summary of Non-clinical tests Conducted for Determination of Substantial Equivalence		
Performance Test Summary – New Device		
Characteristic	**Standard/Test/FDA Guidance**	**Results Summary**
Electromagnetic Compatibility	Compliant with IEC 60601-1-2	Compliant with IEC 60601-1-2
Electrical Safety and Acoustic Safety	Compliant with IEC 60601-1, IEC 60601-1-4, and IEC 60601-2-37	Compliant with IEC 60601-1, IEC 60601-1-4, and IEC 60601-2-37

Conclusions Drawn from Design Verification/Validation and Non-clinical Data
The HD-IVUS Ultrasound Imaging System (with Linear Translation System) is substantially equivalent in design and technology to the predicate device(s) with regard to intended use.

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

JAN 11 2013

Silicon Valley Medical Instruments, Inc. (SVMI)
c/o Richard E. Anderson
47697 Westinghouse Drive, Suite 101
Fremont, CA 94539-7401

Re: K122878
Trade Name: HD-IVUS Ultrasound Imaging System (with Linear Translation System)
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic intravascular catheter
Regulatory Class: Class II
Product Code: QBJ
Dated: December 10, 2013
Received: December 13, 2013

Dear Mr. Anderson:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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,

Owen P. Faris -S

for Bram D. Zuckerman, M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Silicon Valley Medical Instruments Inc.™

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: HD-IVUS Ultrasound Imaging System (with Linear Translation System)

Indications for Use: Silicon Valley Medical Instrument's HD-IVUS Ultrasound Imaging System (Console) is intended for ultrasound examination of coronary intravascular pathology only. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal coronary interventional procedures.

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 Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K122878