Appendix 4: 510(k) Summary per (21CFR807.92)

DEC 7 2012

510(k) Number	K122105	
Submitter Name and Address		
Name:	Solinas Medical, Inc.	
Contact:	Michael Kolber Consultant, Regulatory Affairs	
Address:	443 Costa Mesa Terrace, Unit A Sunnyvale, CA 94085	
Telephone:	650-793-5015	
Fax:	408-720-9466	
Date Prepared:	November 7, 2012	
General Device Information		
Product Name:	SMI Cardiovascular Patch	
Common Name:	Cardiovascular patch	
Classification:	21CFR870.3470	
Classification Name	Intracardiac patch or pledget made of polypropylene, polyethylene terephthalate, or polytetrafluoroethylene	
Device Class:	Class II	
Product Code:	DXZ	
Predicate Device		
Manufacturer	Device Name	510(k) Number
Solinas Medical Inc.	SMI Cardiovascular Patch	K112683
Description		
The SMI Cardiovascular Patch is designed for cardiovascular patching. The SMI Cardiovascular Patch is comprised of a knitted polyethylene terephthalate (polyester) fabric covered silicone sheet and with a thin nickel-titanium (nitinol) alloy mesh. It is provided in various sizes and as flat and curved shapes. The SMI Cardiovascular Patch in the flat configuration is 2 cm x 7.5 cm and the following curved sizes: 6, 7, 8, 9, and 10 mm diameters, 4.5 cm length, and 360° arc angle. A manufacturing change was also made to bond the polyester fabric to the silicone.		
Intended Use (Indications)		
The SMI Cardiovascular Patch is intended for cardiovascular patching.		
Comparison to the Predicate Device		
The predicate SMI Cardiovascular Patch includes a curved configuration of 6mm diameter, 3, 7.5, and 15 cm lengths, and 120° arc angle and flat configuration of 1 and 2 cm width by 3, 7.5, and 15 cm lengths. This submission increases the number sizes available and implements a manufacturing change to securely bond the polyester fabric		

rather than stitching the fabric to the silicone. The SMI Cardiovascular Patch has the same intended use and fundamental scientific technology as the predicate device. The technological characteristics of the SMI Cardiovascular Patch are substantially equivalent to the predicate device including biocompatibility, sterilization, packaging, and labeling. Through bench performance testing it was demonstrated that the additional sizes, dimension changes and manufacturing change does not adversely affect safety and effectiveness.
Summary of Non-clinical Testing
The non-clinical test data provided in this submission demonstrated that the SMI Cardiovascular Patch meets the performance specifications. The submission includes bench mechanical testing, including: Tensile Strength, Burst Strength, Suture Pullout, and Water Permeability Tests. These tests demonstrate the SMI Cardiovascular Patch has results that are substantially equivalent to the predicate device.
Statement of Equivalence
The SMI Cardiovascular Patch has the same indications for use and the same technological characteristics as the predicate device. Based on this and the data provided in this pre-market notification, the subject device and the predicate device have been shown to be substantially equivalent.

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

DEC 7 2012

Solinas Medical, Inc.
C/O James Hong
443 Costa Mesa Terrace
Sunnyvale, CA 94089

Re: K122105
Trade/Device Name: SMI Cardiovascular Patch
Regulation Number: 21 CFR 870.3470
Regulation Name: Intracardiac patch or pledget made of polypropylene, polyethylene terephthalate, or polytetrafluoroethylene
Regulatory Class: Class II
Product Code: DXZ
Dated: November 07, 2012
Received: November 08, 2012

Dear Mr. Hong:

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,

Kenneth J. Cavanaugh

for

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

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: Solinas Medical, Inc. SMI Cardiovascular Patch

Indications for Use: The Solinas Medical, Inc. SMI Cardiovascular Patch is indicated for cardiovascular patching.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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 K122105