DEC 1 4 2011 K112683

510(k) Summary
(per 21CFR807.92)

General Company Information		
Name:	Solinas Medical, Inc.	
Contact:	James Hong President and CEO	
Address:	443 Costa Mesa Terrace, Unit A Sunnyvale, CA 94085	
Telephone:	650-793-5015	
Fax:	408-720-9466	
Date Prepared:	September 13, 2011	
General Device Information		
Product Name:	SMI Cardiovascular Patch	
Common Name:	Cardiovascular patch	
Classification:	21CFR870.3470	
Device Class:	The SMI Cardiovascular Patch has not yet been classified. Based on FDA's classification of this type of device, the SMI Cardiovascular Patch should be classified as a class II device.	
Product Code:	DXZ	
Predicate Devices		
Manufacturer	Device Name	510(k) Number
W.L. Gore & Associates, Inc.	ACUSEAL Cardiovascular Patch	K984526
Meadox Medicals, Inc.	Hemashield Finesse Ultra-thin Knitted Cardiovascular Patch	K962342
C.R. Bard	DeBakey Elastic Knit Fabric	Pre-amendment device
Teleflex, Inc.	Cottony Silky II Polydeck Tevdek	K021019
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 reinforced with a thin sheet of polyester embedded in the silicone and optionally with a thin nickel-titanium (nitinol) alloy mesh. It is provided in various sizes and as flat and curved sheets.		
Intended Use (Indications)		
The SMI Cardiovascular Patch is intended for cardiovascular patching.		
Substantial Equivalence		
The SMI Cardiovascular Patch is substantially equivalent to currently marketed cardiovascular patch devices. Mechanical testing, including: Tensile Strength, Burst Strength, Suture Pullout, and Water Permeability Tests, demonstrates the		

applicant device has strength values that are substantially equivalent to the predicate devices.
Conclusions
Solinas Medical, Inc. believes that the information provided demonstrates that the proposed device is substantially equivalent to the predicate devices and does not raise any new issues of safety or efficacy. Based on the indications for use, technological characteristics, and comparison to predicate devices the SMI Cardiovascular Patch has been shown to be substantially equivalent to predicate devices as described under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC 14 2011

Solinas Medical, Inc.
c/o Michael Kolbe
443 Costa Mesa Terrace
Sunnyvale, CA 94085

Re: K112683
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: September 13, 2011
Received: September 15, 2011

Dear Mr. Kolbe:

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,

M. J. Hillebrenner

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): K112683

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 K112683