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JUL 11 2003

WARNING LETTERFood and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850VIA FACSIMILE
VIA FEDERAL EXPRESSMelvin E. Levinson, M.D.
Chairman/Chief Executive Officer
Scion Cardio-Vascular, Inc.
14256 SW 119 Avenue
Miami, Florida 33186

Re: Clo-Sur Pressure Applied Dressing (P.A.D.)

Dear Dr. Levinson:

The Food and Drug Administration (FDA) has reviewed Scion Cardio-Vascular Inc.'s website at <http://www.scioncv.com> regarding the Clo-Sur Pressure Applied Dressing (P.A.D.)™. This product is a device within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The Center for Devices and Radiological Health (CDRH) sent you a letter dated October 5, 2001, concerning claims being made for this product on your website. We received your response dated October 15, 2001, in which you said you would delete the terms "percutaneous" and "arterial" in the acronym for the Clo-Sur P.A.D.™. This letter brings to your attention statements similar to those cited previously that currently appear on your website and are inconsistent with the terms of the premarket notification exemption granted the Clo-Sur P.A.D.™.

Your firm submitted a 510(k) for the Clo-Sur P.A.D.™ and, based upon the intended use of the device, CDRH classified it as a Hydrophilic Wound Dressing and determined it was exempt from the 510(k) requirements. A hydrophilic wound dressing

is a sterile or non-sterile device intended to cover a wound and to absorb exudates. It consists of nonresorbable materials with hydrophilic properties that are capable of absorbing exudate (e.g., cotton, cotton derivatives, alginates, dextran, and rayon). This classification does not include a hydrophilic wound dressing that contains added drugs such as anti-microbial agents, added biologics such as growth factors, or is composed of materials derived from animal sources.

21 CFR 878.4018.

The information regarding the Clo-Sur P.A.D.™ found at the "Products" link of your website, http://www.scioncv.com/Products_CloSurPAD_Main.html, states that the product "reduces clinician hold time and allows patients to be moved into a recovery area and discharged more rapidly in most cases." Moreover, a "Market Preference Study" available on your website at http://www.scioncv.com/Products_CloSurPAD_Main_MPS.htm and also at <http://www.scioncv.com/brochures/EndoToday.pdf> states: "Control of the arterial access site following percutaneous vascular procedures remains a crucial aspect of both invasive diagnostic and interventional cardiology." The study further discusses the use of the Clo-Sur P.A.D.™ on patients undergoing diagnostic cardiac catheterizations and in patients who had just undergone interventional procedures, and states that "these data confirm the efficacy and usefulness of the 'Clo-Sur P.A.D.' in patients who have undergone procedures involving a femoral arteriotomy."

In addition, a September 9, 2002, press release found at <http://www.scioncv.com/PressReleases.html>, entitled "Scion Cardio-Vascular Announces Agreement With Medtronic For Distribution Of The Clo-Sur P.A.D., An Innovative Device Used For Rapid Bleeding Control After Catheterization," states that the device is used for rapid control of bleeding associated with all vascular access sites. The press release refers to use of the device

for the rapid control of bleeding associated with catheter removal following a catheterization procedure such as coronary stenting, as well as other minimally invasive procedures. For the more than 5.8 million Americans each year who undergo angioplasties, cardiac catheterizations, PTCA, stenting and other minimally invasive procedures, the Clo-Sur P.A.D. represents a dramatic step forward in the healing process.

These materials suggest that this topical device can be used following a catheterization lab procedure to achieve closure of the arterial puncture site. Such uses are not included within the cleared intended uses for hydrophilic wound dressings. We invite you to submit a 510(k) to support the use of the Clo-Sur P.A.D.™ for closure of the femoral artery site; however, in the absence of 510(k) clearance for this use, your promotion of the Clo-Sur P.A.D.™ for this use creates a new intended use for this device that is not cleared by the FDA.

Your continued promotion and introduction into interstate commerce of the Clo-Sur P.A.D.™ for this uncleared and unapproved indication renders the device adulterated under section 501(D)(1)(B) of the Act, for failure to obtain FDA premarket approval, and misbranded under section 502(o) of the Act, for failure to notify the agency of your intent to introduce the devices into commercial distribution, as required by section 510(k) of the Act. Distribution in interstate commerce of misbranded or adulterated devices is prohibited by law under section 301 of the Act.

This letter is not intended to be an all-inclusive list of deficiencies associated with your devices. It is your responsibility to ensure adherence to each requirement of the Act and regulations for every FDA-regulated product that you market. You are responsible for investigating and reviewing all materials to ensure compliance with applicable regulations.

You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil money penalties. Also, Federal agencies are informed about the Warning Letters we issue, such as this one, so that they may consider this information when awarding government contracts.

Please notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Melvin E. Levinson, M.D.
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You may direct your response to the above issues to Patricia L. Jahnes, Consumer Safety Officer, Division of Enforcement A (HFZ-332), Office of Compliance, Center for Devices and Radiological Health, at the letterhead address.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Larry D. Spear for".

Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices and
Radiological Health