



APR 30 2010

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

Closure Medical Corporation
% Mr. W. Thomas Stephens
Senior Regulatory Programs Manager
5250 Greens Dairy Road
Raleigh, North Carolina 27616

Re: K082289
PRINEO Skin Closure System
Evaluation of Automatic Class III Designation
Regulation Number: 21 CFR 878.4011
Classification: II
Product Code: OMD

Dear Mr. Stephens:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your Evaluation of Automatic Class III Designation petition (de novo) for classification of the PRINEO Skin Closure System, a prescription device under 21 CFR Part 801.109 that is indicated for topical application only to hold closed easily approximated skin edges of wounds from surgical incisions, including punctures from minimally invasive surgery, and simple, thoroughly cleansed, trauma-induced lacerations. It may be used in conjunction with, but not in place of, deep dermal stitches. Additionally, the adjunct wound closure device component maintains temporary skin edge alignment along the length of the wound during application of the liquid adhesive. FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies your device, the PRINEO Skin Closure System, and substantially equivalent devices of this generic type into class II under the generic name, Tissue Adhesive with Adjunct Wound Closure Device Intended for Topical Approximation of Skin.

FDA identifies this generic type of device as:

“A tissue adhesive with adjunct wound closure device intended for the topical approximation of skin is a device indicated for topical application only to hold closed easily approximated skin edges of wounds from surgical incisions, including punctures from minimally invasive surgery, and simple, thoroughly cleansed, trauma-induced lacerations. It may be used in conjunction with, but not in place of, deep dermal stitches. Additionally, the adjunct wound closure device component maintains temporary skin edge alignment along the length of the wound during application of the liquid adhesive.

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(1)) (the act), devices that were not in commercial distribution prior to May 28, 1976 (the

date of enactment of the Medical Device Amendments of 1976 (the amendments)), generally referred to as post amendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act (21 U.S.C. 360c(i)), to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and Part 807 of the FDA regulations (21 CFR 807).

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) for a device may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1), request FDA to classify the device under the criteria set forth in section 513(a)(1). FDA shall, within 60 days of receiving such a request classify the device type. This classification shall be the initial classification of the device type. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register classifying the device type.

On March 24, 2009, FDA filed your petition requesting classification of your device, the PRINEO Skin Closure System, into class II. The petition was submitted under section 513(f)(2) of the act. In accordance with section 513(f)(1) of the act, FDA issued an order on February 25, 2009 automatically classifying your device, the PRINEO Skin Closure System into class III, because it was not within a type of device which was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, which was subsequently reclassified into class I or class II. In order to classify the PRINEO Skin Closure System into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device type for its intended use.

After review of the information submitted in the petition, FDA has determined that your device, the PRINEO Skin Closure System, indicated “for topical application only to hold closed easily approximated skin edges of wounds from surgical incisions, including punctures from minimally invasive surgery, and simple, thoroughly cleansed, trauma-induced lacerations. It may be used in conjunction with, but not in place of, deep dermal stitches. Additionally, the adjunct wound closure device component maintains temporary skin edge alignment along the length of the wound during application of the liquid adhesive” can be classified in class II with the establishment of special controls for class II. FDA believes that class II special controls provide reasonable assurance of the safety and effectiveness of the device type.

In addition to the general controls of the act, your device, the PRINEO Skin Closure System, is subject to the following special controls: the guidance document entitled, “Class II Special Controls Guidance Document: Tissue Adhesive with Adjunct Wound Closure Device Intended

for the Topical Approximation of Skin,” to address the specific risks to health associated with a tissue adhesive with adjunct wound closure device intended for the topical approximation of skin. The risks identified in the “Class II Special Controls Guidance Document: Tissue Adhesive with Adjunct Wound Closure Device Intended for the Topical Approximation of Skin” are: unintentional bonding of device due to misapplication of device, device leaking or running to unintended areas, etc.; wound dehiscence; adverse tissue reaction and chemical burns; infection; applicator malfunction; weak bonding leading to loss of approximation; and delayed polymerization.

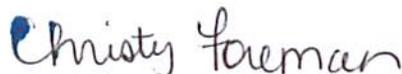
Section 510(m) of the act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements. Thus, persons who intend to market this device must submit to FDA a premarket notification submission containing information on the tissue adhesive with adjunct wound closure device intended for the topical approximation of skin they intend to market prior to marketing the device and receive clearance from FDA prior to marketing.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market this device, subject to the general control provisions of the act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact George J. Mattamal, Ph.D. at (301) 796-6396.

Sincerely yours,

A handwritten signature in blue ink that reads "Christy Foreman". The signature is written in a cursive, flowing style.

Christy L. Foreman, M.S.
Deputy Director for Science and Review Policy
Office of Device Evaluation
Center for Devices and Radiological Health