WARNING LETTER

Surgisil, LLP

MARCS-CMS 567886 — 15/04/2019

Product:

Medical Devices
Premarket Approval (PMA)
General & Plastic Surgery

Recipient:

Peter Raphael, MD
Chief Executive Officer
Surgisil, LLP
6020 W. Plano Parkway
Plano, TX 75093
United States

Issuing Office:

Office of Medical Device and Radiological Health Operations
Division 3 West
19701 Fairchild
Irvine, CA 92612
United States

UNITED PARCEL SERVICE
OVERNIGHT DELIVERY

WARNING LETTER
CMS: 567886

April 15, 2019

Peter Raphael, MD, Chief Executive Officer
Surgisil, LLP
6020 W. Plano Parkway
Plano, TX 75093

Dear Dr. Raphael,

The United States Food and Drug Administration (FDA) conducted an inspection of your firm's medical device operations at 6020 W. Plano Parkway, Plano, TX 75093 from September 20 - 25, 2018. During the inspection, an FDA investigator determined that your firm is a manufacturer of the Perma Facial Implant. Under section 201 (h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321 (h), this product is a device because it is intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body.

Our inspection, and review of materials collected during the inspection, revealed that the Perma Facial Implant is adulterated under section 501 (f)(1)(B) of the Act, 21 U.S.C. § 351 (f)(1)(B), because you do not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), or an approved application for an investigational device exemption (IDE) under section 520(g) of the Act, 21 U.S.C. § 360j(g).

Your firm has a cleared 510(k) for the Perma Facial Implant "intended for use in plastic and reconstructive surgery. The devices can be used for cosmetic augmentation and corrections in the face, including areas such as the nose, chin, and cheeks" (K071823). The applicable classification regulation, 21 CFR 878.3500, states, in part, that these types of devices are "intended to be implanted during surgery of the chin, jaw, nose, or bones or tissue near the eye or ear." However, our inspection and review of your firm's instructional videos and training materials reveal that your firm is marketing the Perma Facial Implant for augmentation of the lips, which constitutes a major change/modification to its intended use for which you lack approval.
Examples include:

Perma™ Facial Implant Instructional Video
• This is a 3-minute instructional video titled "Perma™ Facial Implant Instructional Video" covering

the materials and procedures for use of the Perma Facial Implant in lip augmentation. The images show, and the narrative describes, the implant of the Perma Facial Implant in the upper and lower lips of a live patient.

SurgiSil™ Surgeon Training Checklist, Medical Director/Surgeon Phone Training Checklist
• This is a 12-item checklist documenting the training provided to medical directors and surgeons on the use of the Perma Facial Implant. The process described in the training checklist is for implantation of the Perma Facial Implant in the lips. For example, Item #5 in the training checklist states, "[r]oll the lip up such that the wet dry border faces up toward the ceiling during dissection I to help surgeon not veer from the wet I dry border."

The lips are physiologically and anatomically different from the nose, chin, and cheeks, including in vascularity, high mobility, and bone support. Use of the Perma Facial Implant in augmentation of the lips may cause migration or protrusion of the implant. Due to lack of bone structure in the lips, the implanted device can "free float" when compared to implantation in the other organs and thereby leading to migration and protrusion. Furthermore, since the lips are very actively used, the free-floating nature of implanted devices exacerbates risks such as device extrusions, which when occur, may require surgical removal and extensive dermal repair. Migration and protrusion also increase other risks to the patient, such as infection and chronic pain. Augmentation of the lips is a major change or modification in intended use that does not fall within the Perma Facial lmplant's current clearance.

Your firm **(b)(4)** your firm continues to market the Perma Facial Implant for augmentation of the lips.

Additionally, we note that a review of your firm 's website (www.surgisil.com/us/) revealed that the labeling of the device, namely its promotional materials, contains statements that are misleading in accordance with 21 CFR 807.97, because such statements create an impression of official approval of a device due to clearance of a premarket notification submission. Specifically, the "Products" page on your firm's website states that the "Perma Facial Implant™ is a patented, FDA approved device designed for tissue augmentation of the face and has undergone extensive clinical testing to ensure its safety and efficacy." The Perma Facial Implant was not approved by the FDA, but was determined to be substantially equivalent within the meaning of section 513(i)(1)(A) of the Act, 21 U.S.C. § 360c(i)(1)(A). We request that you remove from your firm's website the statement that "FDA approved [the] device."

We also note that a review of your firm's website (www.surgisil.com/us/) revealed that your firm is currently marketing an unapproved device, the PermaLip Implant. Specifically, on the "Events" page of your firm's website, it states that your firm will be exhibiting at both The Aesthetic Meeting 2019 and the Vegas Cosmetic Surgery Conference 2019 and that attendees should "say hello and learn more about our flagship products - Permalip and the Perma Facial Implant." The Permalip Implant is not cleared or approved by FDA for marketing in the United States.

We have not received any written response to our inspection as of the date of this letter.

Our office requests that your firm immediately cease activities that result in the misbranding or adulteration of the Perma Lip Implant, such as the commercial distribution of the device for the uses discussed above.

Your firm should take prompt action to correct the violations addressed in this letter. 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 civil money penalties. Also, federal agencies may be advised of the issuance of Warning Letters about devices so that they may take this information into account when considering the award of contracts.

Please notify this office in writing within fifteen business days from the date you receive this letter of the specific steps your firm has taken to correct the noted violations, as well as an explanation of how your firm plans to prevent these violations, or similar violations, from occurring again. Include documentation of the corrections and/or corrective actions (including any systemic corrective actions) that your firm has taken. If your firm's planned corrections and/or corrective actions will occur over time, please include a timetable for implementation of those activities. If corrections and/or corrective actions cannot be completed within fifteen business days, state the reason for the delay and the time within which these activities will be completed. Your firm's response should be comprehensive and address all violations included in this Warning Letter. If you have evidence or information that you believe demonstrate that your product is not in violation of the FD&C Act, include that evidence or information for our consideration.

Your firm's response should be sent via e-mail to: US Food and Drug Administration, Division 3/West, Office of Medical Device and Radiological Health Operations at ORADevices3FirmResponse@fda.hhs.gov. Please identify your response with FEI 3006007116. If you have any questions about the contents of this letter, please contact Compliance Officer Jeff R. Wooley at 214-253-5251, or via e-mail at Jeffrey.wooley@fda.hhs.gov

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your firm's facility. It is your firm's responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Inspectional Observations, FDA 483, issued at the close of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality management systems. Your firm should investigate and determine the causes of the violations, and take prompt actions to correct the violations and bring the products into compliance.

Sincerely,
/S/
Shari J. Shambaugh
Program Division Director

Office of Medical Device and Radiological Health
Division 3 West

Content current as of:
04/30/2019

Regulated Product(s)
Medical Devices
Premarket Approval (PMA)
General & Plastic Surgery

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