



[Home](#) > [Inspections, Compliance, Enforcement, and Criminal Investigations](#) > [Enforcement Actions](#) > [Warning Letters](#)

## Inspections, Compliance, Enforcement, and Criminal Investigations

### LifeCell Corporation



Department of Health and Human Services

Public Health Service  
Food and Drug Administration

May 5, 2011

### WARNING LETTER

#### VIA UPS EXPRESS

Darryl A. Roberts, Ph.D.  
Vice President, Quality and Regulatory Affairs  
LifeCell Corporation  
One Millennium Way  
Branchburg, NJ 08876-3876

Dear Dr. Roberts:

This Warning Letter is to inform you of objectionable conditions observed during the Food and Drug Administration (FDA) inspection conducted at LifeCell Corporation from November 2, 2010, to November 12, 2010, by investigators from the FDA New Jersey District Office. The purpose of this inspection was to determine whether LifeCell's activities as sponsor of the clinical study "A Prospective, Multicenter, Randomized, Controlled, Third Party-Blinded Study of Strattice Fascial Inlay to Prevent Parastomal Hernia Formation in Patients Undergoing Surgery for Permanent Abdominal Wall Ostomies (PriSm)" complied with applicable federal regulations.

The Strattice, LifeCell Tissue Matrix (LTM) Surgical Mesh ("Strattice"), is a device as that term is defined in Section 201(h) (21 U.S.C. 321(h)) of the Federal Food, Drug, and Cosmetic Act (the Act), because it is intended for the use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, or is intended to affect the structure or function of the body. FDA cleared the device under Premarket Notification Submissions (510(k)s) K070560, K071986, and K080353. This letter requests prompt corrective action to address the violations cited and discusses your written response, dated December 1, 2010, to the noted violations.

The inspection was conducted under a program designed to ensure that data and information contained in requests for Investigational Device Exemptions (IDE), Premarket Approval (PMA) applications, and Premarket Notification submissions (510(k)) are scientifically valid and accurate. Another objective of the program is to ensure that human subjects are protected from undue hazard or risk during the course of scientific investigations.

Our review of the inspection report prepared by the district office revealed serious violations of Title 21, **Code of Federal Regulations** (21 CFR) Part 812--Investigational Device Exemptions, and Section 520(g) (21 U.S.C. 360j(g)) of the Act. At the close of the inspection, the FDA investigator presented an inspectional observations Form FDA 483 for your review and discussed the observations listed on the form with you. The deviations noted

on the Form FDA 483, your written response, and our subsequent review of the inspection report are discussed below:

**1. Failure to submit an application to the FDA and obtain approval prior to allowing subjects to participate in the investigation. [21 CFR 812.20(a)(1) and (a)(2), 21 CFR 812.40, 21 CFR 812.42]**

A sponsor is required to submit an IDE application to FDA and obtain FDA approval of the application prior to allowing subjects to participate in an investigation of a significant risk device. You failed to adhere to the above-stated regulations. An example of your failure includes, but is not limited to, the following:

You failed to submit an IDE application to FDA and obtain FDA approval before allowing subjects to participate in the study, "A Prospective, Multicenter, Randomized, Controlled, Third Party-Blinded Study of Strattice Fascial Inlay to Prevent Parastomal Hernia Formation in Patients Undergoing Surgery for Permanent Abdominal Wall Ostomies (PriSm)." Specifically, you permitted the Strattice device, a significant risk device (as defined in 21 CFR 812.3(m)(1)), because it is intended as an implant and presents the potential for serious risk to the health, safety, or welfare of a subject, to be implanted in approximately **(b)(4)** subjects enrolled in the study without submitting an IDE application to FDA or obtaining FDA approval.

FDA does not consider this investigation to meet the requirements of an exempted investigation under 21 CFR 812.2(c). FDA cleared the Strattice surgical mesh device under premarket notification K070560 for use "as a soft tissue patch to *reinforce* soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes. Indications for use include the repair of hernias and/or body wall defects which *require* the use of reinforcing or bridging material to obtain the desired surgical outcome" (emphasis added). However, in this investigation, the device was being studied for use to prevent (not reinforce) parastomal hernias, and for cases where use of a bridging or reinforcing material is not required (unlike the FDA-cleared indications for use where use of a bridging or reinforcing material is required). Accordingly, this study falls outside the FDA-clearance for the device, and therefore is not exempted under 21 CFR 812.2(c).

This investigation is not considered to have an approved application for IDE under 21 CFR 812.2(b) as it concerns a significant risk device.

FDA issued you a letter on October 7, 2010, informing you that you were required to submit an IDE application for the study, "A Prospective, Multicenter, Randomized, Controlled, Third Party-Blinded Study of Strattice Fascial Inlay to Prevent Parastomal Hernia Formation in Patients Undergoing Surgery for Permanent Abdominal Wall Ostomies (PriSm)." To date, you have not done so. Your response, dated December 1, 2010, to the form FDA 483, is inadequate in that it fails to acknowledge that the clinical trial requires an IDE and FDA approval of the IDE.

**2. Failure to submit an application to the FDA and obtain approval prior to allowing subjects to participate in the investigation. [21 CFR 812.20(a)(1) and (a)(2), 21 CFR 812.40, 21 CFR 812.42]**

You failed to submit an IDE application to FDA and obtain FDA approval before allowing subjects to participate in the study, "A Multicenter, Prospective, Open-Label Study to Assess the Clinical Outcomes of LTM Use in Two-Stage Breast Reconstruction Immediately Post-Mastectomy." Specifically, you permitted the Strattice device, a significant risk device (as defined in 21 CFR 812.3(m)(1)), because it is intended as an implant and presents potential for serious risk to the health, safety, or welfare of a subject, to be implanted in **(b)(4)** subjects without submitting an IDE application to FDA and obtaining FDA approval.

FDA does not consider this investigation to meet the requirements of an exempted investigation under 21 CFR 812.2(c). FDA cleared the device under premarket notification K082176, for use in "*reinforcement* of soft tissues in plastic and reconstructive surgery." However, in this investigation, the device is not being used for "*reinforcement*" of soft tissues, but rather as a "*replacement*" in conjunction with Class III breast implants. Accordingly, this study falls outside the FDA clearance for the device, and therefore is not exempted under 21 CFR 812.2(c).

This investigation is not considered to have an approved application for IDE under 21 CFR 812.2(b) as it concerns a significant risk device.

**3. Failure to submit an application to the FDA and obtain approval prior to allowing subjects to participate in the investigation. [21 CFR 812.20(a)(1) and (a)(2), 21 CFR 812.40, 21 CFR 812.42]**

You failed to submit an IDE application to FDA and obtain FDA approval before allowing subjects to participate in the study, "A Multicenter, Prospective, Observational Evaluation of Repair of Infected or Contaminated Hernias

(RICH) using LTM (Strattice).” Specifically, you permitted the Strattice device, a significant risk device (as defined in 21 CFR 812.3(m)(1)), because it is intended as an implant and presents potential for serious risk to the health, safety, or welfare of a subject, to be implanted in **(b)(4)** subjects without submitting an IDE application to FDA and obtaining FDA approval.

FDA does not consider this investigation to meet the requirements of an exempted investigation under 21 CFR 812.2(c). FDA cleared the device under premarket notification K082103, for use in *management* of wounds and *support* of wound healing and control of minor bleeding. The device has not been cleared or approved for use to repair infected or contaminated hernias. Accordingly, this study falls outside the FDA clearance for the device, and therefore is not exempted under 21 CFR 812.2(c).

Additionally, this investigation is not considered to have an approved application for IDE as it concerns a significant risk device.

**4. Failure to comply with FDA regulations that prohibit promotion of an investigational device until after FDA has approved the device for commercial distribution and representation that an investigational device is safe or effective for the purposes for which it is being investigated. [21 CFR 812.7(a) and (d)]**

A sponsor, investigator, or any person acting for or on behalf of a sponsor or investigator shall not promote or test market an investigational device, until after FDA has approved the device for commercial distribution, and shall not represent that an investigational device is safe or effective for the purposes for which it is being investigated. You have failed to adhere to the above-stated regulations. Examples of your failure include, but are not limited to, the following:

Your clinical investigation entitled, “A Multicenter, Prospective, Open-Label Study to Assess the Clinical Outcomes of LTM Use in Two-Stage Breast Reconstruction Immediately Post-Mastectomy,” is studying the use of the Strattice device in two-stage breast reconstruction immediately post-mastectomy. The investigation involves use of the Strattice device as a “replacement” for soft tissue in conjunction with Class III breast implants. The section of your website ([www.lifecell.com](http://www.lifecell.com)<sup>1</sup>, accessed on April 25, 2011), entitled “Using AlloDerm or Strattice Tissue Matrices,” states that Life Cell Tissue Matrices: “Provide an additional layer of tissue that may help hide implant visibility. Help control the location of the implant and to define the breast fold. Support the implant which may help prevent bottoming out (downward movement of the implant) or extrusion of the implant through the skin.” The webpage provides pictures of the “Strattice Reconstructive Tissue Matrix Results” at preoperative, 2 weeks, 4 months, and 6 months after use of the device. FDA considers these statements to constitute promotion of the Strattice device for use with breast implants, a use for which it is being investigated and for which it has not been cleared or approved by FDA, in violation of 21 CFR 812.7(a), and to represent that the Strattice device is safe and effective for an indication that it is being investigated, in violation of 21 CFR 812.7(d).

Marketing the Strattice device for the uses described above constitutes a significant change in the intended use of the device that requires the submission of a new 510(k). 21 CFR 807.81(a)(3)(ii). Such promotion renders the Strattice device 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 PMA application in effect pursuant to section 515(a) of the Act (21 U.S.C. 360e(a)). The device is also misbranded under section 502(o) of the Act (21 U.S.C. 352(o)), because you did not notify the agency of your intent to introduce the device into commercial distribution for the changed uses described above, as required by section 510(k) of the Act (21 U.S.C. 360(k)). For a device requiring premarket approval, the notification required by section 510(k) of the Act (21 U.S.C. 360(k)), is deemed satisfied when a PMA is pending before the Agency. 21 CFR 807.81(b).

Your response is inadequate in that it fails to acknowledge that you are promoting the Strattice device for a use that is investigational and subject to the regulations of 21 CFR Part 812, and that has not been cleared or approved by FDA.

The violations described above are not intended to be an all inclusive list of problems that may exist with your clinical studies. It is your responsibility as a study sponsor to ensure compliance with the Act and applicable regulations.

Within fifteen working days of receiving this letter, please provide written documentation of the additional actions you have taken or will take to correct these violations and prevent the recurrence of similar violations in current or future studies for which you are the study sponsor. Any submitted corrective action plan must include projected completion dates for each action to be accomplished. Failure to respond to this letter and take

appropriate corrective action could result in the FDA taking regulatory action without further notice to you.

Your response should reference "CTS # K070560/E001" and be sent to:

Attention: Anne T. Hawthorn  
Food and Drug Administration  
Center for Devices and Radiological Health  
Office of Compliance  
Division of Bioresearch Monitoring  
10903 New Hampshire Avenue  
Building 66, Room 3504  
Silver Spring, Maryland 20993-0002.

*A copy of this letter has been sent to FDA's New Jersey District Office, 10 Waterview Blvd, 3<sup>rd</sup> Floor, Parsippany, NJ 07054. Please send a copy of your response to that office.*

The Division of Bioresearch Monitoring has developed introductory training modules in FDA-regulated device clinical research practices, which are available on the FDA website. The modules are for persons involved in FDA-regulated device clinical research activities. These modules are located at the following website address: <http://www.fda.gov/Training/CDRHLearn/ucm162015.htm><sup>2</sup>.

If you have any questions, please contact Anne T. Hawthorn at 301-796-6561, [Anne.Hawthorn@fda.hhs.gov](mailto:Anne.Hawthorn@fda.hhs.gov).

Sincerely yours,  
/S/  
Steven D. Silverman  
Director  
Office of Compliance  
Center for Devices and  
Radiological Health

---

**Links on this page:**

1. <http://www.lifecell.com/>
2. <http://www.fda.gov/Training/CDRHLearn/ucm162015.htm>