# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**Washington, D.C. 20549**

# FORM 8-K

**CURRENT REPORT**
**Pursuant to Section 13 or 15(d)**
**of the Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported): September 24, 2013**

# INTEGRA LIFESCIENCES HOLDINGS CORPORATION
**(Exact name of Registrant as specified in its charter)**

| **Delaware** | **0-26224** | **51-0317849** |
|---|---|---|
| **(State or other jurisdiction of incorporation or organization)** | **(Commission File Number)** | **(I.R.S. Employer Identification No.)** |

**311 Enterprise Drive**
**Plainsboro, NJ 08536**
**(Address of principal executive offices) (Zip Code)**

**Registrant's telephone number, including area code: (609) 275-0500**

**Not Applicable**
**(Former name or former address, if changed since last report)**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

**Item 8.01 Other Events.**

On September 24, 2013, the United States Food and Drug Administration (the “FDA”) issued a letter to Integra LifeSciences Corporation, a wholly-owned subsidiary of Integra LifeSciences Holdings Corporation (the “Company”) informing the Company that it had addressed the violations in the FDA warning letter dated December 21, 2011 related to the Company’s regenerative medicine facility in Plainsboro, New Jersey (the “Plainsboro Facility”) and that such warning letter had been closed out effective September 24, 2013. A copy of the letter dated September 24, 2013 relating to the resolution of the warning letter matters is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

The press release issued by the Company on September 26, 2013 announcing the resolution of the FDA warning letter related to the Plainsboro Facility is attached as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated by reference herein.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

| | |
|---|---|
| 99.1 | Letter, dated September 24, 2013, from the United States Food and Drug Administration to Integra LifeSciences Corporation |
| 99.2 | Press Release issued September 26, 2013 |

## EXHIBIT INDEX

| Exhibit Number | Exhibit |
| --- | --- |
| 99.1 | Letter, dated September 24, 2013, from the United States Food and Drug Administration to Integra LifeSciences Corporation |
| 99.2 | Press Release issued September 26, 2013 |

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

INTEGRA LIFESCIENCES HOLDINGS CORPORATION

Date: September 27, 2013

By: /s/ John B. Henneman, III
John B. Henneman, III
Title: Corporate Vice President, Finance and Administration, and Chief Financial Officer

**Exhibit 99.1**

Department of Health and Human Services

Food and Drug Administration
New Jersey District Office
Central Region
Waterview Corporate Center
10 Waterview Blvd. 3rd Floor
Parsippany, New Jersey 07054
Telephone: (973) 331-4900
FAX: (973) 331-4969

September 24, 2013

Integra LifeSciences Corporation
Attention: Peter J. Arduini, President & CEO
311 Enterprise Drive
Plainsboro, New Jersey 08536

Dear Mr. Arduini:

The Food and Drug Administration has completed an evaluation of your corrective actions in response to our Warning Letter 12-NWJ-04, dated December 21, 2011. Based on our evaluation, it appears that you have addressed the violation(s) contained in this Warning Letter. Future FDA inspections and regulatory activities will further assess the adequacy and sustainability of these corrections.

This letter does not relieve you or your firm from the responsibility of taking all necessary steps to assure sustained compliance with the Federal Food, Drug, and Cosmetic Act and its implementing regulations or with other relevant legal authority. The Agency expects you and your firm to maintain compliance and will continue to monitor your state of compliance. This letter will not preclude any future regulatory action should violations be observed during a subsequent inspection or through other means.

Sincerely,
/S/
Capt. Joseph F. McGinnis
Director Compliance Branch
New Jersey District

**Exhibit 99.2**

*News Release*

Contacts:

Integra LifeSciences Holdings Corporation

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Corporate Vice President,
Finance and Administration
& Chief Financial Officer
(609) 275-0500

Investor Relations:
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*Integra LifeSciences Announces Resolution of Warning Letter Related to Its Plainsboro, NJ, Manufacturing Facility*

Plainsboro, NJ / September 26, 2013 / — Integra LifeSciences Holdings Corporation (Nasdaq: IART) today announced that the United States Food and Drug Administration ("FDA") has informed the Company that it had addressed the violations in the warning letter relating to its Plainsboro, New Jersey manufacturing facility, and that the warning letter had been closed out effective September 24, 2013.

The Plainsboro facility had been operating subject to an FDA Warning Letter dated December 21, 2011, that related to quality systems and compliance issues. After concluding its recent inspection of that facility in August, the FDA determined that the Company's remediation activities were effective and its quality management system was adequate.

"The successful lifting of the Warning Letter related to our Plainsboro, NJ, manufacturing facility is a measure of the progress we have made toward transforming our quality systems around the Company," said Peter Arduini, Integra's President and Chief Executive Officer. "The investments we have made, and will continue to make, are producing results that are fundamental to our long-term goals for the Company ."

Integra LifeSciences, a world leader in medical technology, is dedicated to limiting uncertainty for surgeons, so they can concentrate on providing the best patient care. Integra offers innovative solutions in orthopedic extremity surgery, neurosurgery, spine surgery, and reconstructive and general surgery. For more information, please visit www.integralife.com