

INTEGRA LIFESCIENCES HOLDINGS CORP
Form 8-K
October 06, 2014

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 30, 2014

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 30, 2014, the United States Food and Drug Administration (the “FDA”) completed an inspection of the medical devices manufacturing facility in Añasco, Puerto Rico (the “Añasco Facility”) of Integra LifeSciences Corporation, a wholly-owned subsidiary of Integra LifeSciences Holdings Corporation (the “Company”). The Añasco Facility is operating subject to an FDA warning letter dated February 13, 2013 (the “Warning Letter”) that relates to quality systems and compliance issues. The inspection began on September 4, 2014 and focused primarily on the issues raised in the Warning Letter and in previous inspections of the Añasco Facility. At the conclusion of the inspection, the FDA found that the Company had addressed the issues raised in the Warning Letter and previous inspectional observations, and it issued no other inspectional observations. In reaching this conclusion, the FDA determined that the Company’s remediation activities were effective and its quality management system was adequate.

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: October 6, 2014

By: /s/ Glenn G. Coleman
Glenn G. Coleman

Title: Corporate Vice President and Chief Financial Officer