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): November 13, 2012

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 7.01 REGULATION FD DISCLOSURE

Attached as Exhibit 99.1 and incorporated into this Item 7.01 by reference is the warning letter, dated November 1, 2012, from the United States Food and Drug Administration (the "FDA") to Integra NeuroSciences Ltd., a wholly-owned indirect subsidiary of Integra LifeSciences Holdings Corporation (the "Company"). The warning letter related to quality systems issues at its manufacturing facility located in Andover, England. The letter, which was received on November 5, 2012, resulted from an inspection held at that facility in June 2012.

The warning letter does not restrict the Company's ability to manufacture or ship products or import them in to the United States. It also does it require the recall of products. The Company has provided detailed responses to the FDA as to its corrective actions on a monthly basis and, since the conclusion of the inspection, has undertaken significant efforts to remediate the observations.

The Andover facility manufactures components of the CUSA ultrasonic aspirator system, and intracranial pressure monitors. Sales of products manufactured in the Andover facility constituted less than 3% of the Company's consolidated revenues in the twelve months ended September 30, 2012. The Company does not expect to incur material incremental expense in the fourth quarter of 2012 on remediation activities.

The Company disclosed the warning letter in a press release issued concurrently with the filing of this Current Report on Form 8-K.

The information contained in Item 7.01 of this Current Report on Form 8-K is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that Section. The information contained in Item 7.01 of this Current Report on Form 8-K shall not be incorporated by reference into any registration statement or other document pursuant to the Securities Act or the Exchange Act, except as shall be expressly set forth by specific reference in any such filing.

9.01. FINANCIAL STATEMENTS AND EXHIBITS.

(d) Exhibits.

Exhibit Number	Description of Exhibit
99.1	Letter dated November 1, 2012 from the United States Food and Drug Administration to Integra NeuroSciences Ltd.

SIGNATURES

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

INTEGRA LIFESCIENCES HOLDINGS CORPORATION

Date: November 13, 2012

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

Exhibit Index

Exhibit Number	Description of Exhibit
99.1	Letter dated November 1, 2012 from the United States Food and Drug Administration to Integra NeuroSciences Ltd.

DEPARTMENT OF HEALTH & HUMAN SERVICES

NOV 1 2012

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

WARNING LETTER

VIA UNITED PARCEL SERVICE

Mr. Wenzel Hurtak
Vice President — European Operations
Integra NeuroSciences Ltd.
Newbury Road, Andover
Hampshire SP10 4DR
England

Dear Mr. Hurtak:

During an inspection of your firm located in Hampshire, England, on June 11 through June 14, 2012, an investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures Intracranial Pressure Monitors and Ultrasonic Aspiration devices. Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(h), these products are devices because they are 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 function of the body.

This inspection revealed that these devices are adulterated within the meaning of section 501(h) of the Act, 21 U.S.C. § 351(h), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the current good manufacturing practice requirements of the Quality System regulation found at Title 21, Code of Federal Regulations (CFR), Part 820. We received a response from Peter J. Arduini, President and Chief Operating Officer, Integra LifeSciences Corp., dated July 3, 2012 concerning our investigator's observations noted on the Form FDA 483 (FDA 483), List of Inspectional Observations, which was issued to your firm. We address this response below, in relation to each of the noted violations. These violations include, but are not limited to, the following:

1. Failure to establish and maintain adequate procedures for implementing corrective and preventive action (CAPA), as required by 21 CFR 820.100(a). For example:

a) There is no requirement in your firm's procedure for analysis of quality data to identify existing or potential causes of nonconforming product or other quality problems, using appropriate statistical methodology where necessary.

b) Your firm's Corrective Action Preventative Action Process Procedure (SOP 17.2) requires an effectiveness check that is a valid method of assessment that the root cause has been addressed for the corrective/preventative actions proposed. However, five out of ten CAPAs reviewed did not include a completed and/or valid effectiveness check (i.e., 0057, 0021, 0037, 02/11/10, and 01/01/11).

c) Appendix A to SOP 17.2 includes trigger points for opening a CAPA. One trigger point involves repeated customer complaints related to similar issues. Of the 63 complaints reviewed from 2011 and 2012, the investigator noted four that were related to the cord becoming detached from the selector hand piece and three that reported a vibration alarm related to the CUSA hand piece. However, no CAPAs were opened to address these issues.

d) Your firm has not addressed continuing complaints received due to over-torqueing of the CUSA hand piece when the tip is inserted by the user. The inspection noted that thirteen out of 63 complaints reviewed related to over-torqueing, including at least four that reported overheating of the hand piece. The original CAPA (February 11, 2010) was opened November 10, 2010, to investigate reports of over-torqueing by users of the CUSA hand piece. No information has been added to the CAPA since March 28, 2011, and the CAPA was never closed by the firm.

The adequacy of your firm's response cannot be determined at this time. Your firm provided a detailed list of corrective actions, but it did not provide completion dates or documentation to show that it had implemented these corrective actions.

2. Failure to adequately ensure, when the results of a process cannot be fully verified by subsequent inspection and test, that the process shall be validated with a high degree of assurance and approved according to established procedures, as required by 21 CFR 820.75(a).

For example, your firm's Qualification of Materials, Equipment Processes and Products (SOP 11.3) defines process validation as a method for establishing documented evidence in protocol and report form that a process will consistently produce acceptable product under normal operating conditions. However, there is no documentation to demonstrate validation of the manufacturing process for tips used with the Selector ultrasonic aspiration device. The tips (1523048, 1523082, and 1529012) are manufactured on the CNC machine (i.e., Star Machine). First Article Inspections are performed along with hourly inspections of the tips and functional tests are performed at the end of the manufacturing process; however, full verification, to include dimensional measurements of the tips manufactured, is not performed.

The adequacy of your firm's response cannot be determined at this time. Your firm provided a detailed plan to correct the deficiencies but did not submit any documentation to show that the corrective actions have been implemented.

3. Failure to establish adequate procedures for quality audits and conduct such audits to assure that the quality system is in compliance with established quality system requirements and to determine the effectiveness of the quality system, as required by 21 CFR 820.22. For example, your firm's internal Quality Audits procedure (SOP 17.1) states that the maximum close-out period related to nonconformances found during internal audits is one calendar month. Review of the Audit Plan and completed Audit Schedule, along with the audit close-out sheets for 2010 and 2011, noted that several nonconformances had not been closed within the one calendar month timeframe. In addition, seven out of 13 audits conducted in 2012 were not closed within the one calendar month timeframe.

The adequacy of your firm's response cannot be determined at this time. Your firm provided a detailed plan to correct the deficiencies, but did not provide completion dates or documentation to show that it had implemented the corrective actions.

4. Failure to adequately review the suitability and effectiveness of the quality system at defined intervals and with sufficient frequency according to established procedures to ensure that the quality system satisfies the requirements of Part 820 and the manufacturer's established quality policy and objectives, as required by 21 CFR 820.20(c). For example, your firm's Quality Management Review procedure (SOP 1.2) states that invited participants, if unable to attend the Quality Management Review Meeting, must send a designee in their place. The individuals to be invited to the Quality Management Review, per the procedure, include: Plant Manager, Quality & Regulatory, Production, Operations, Engineering, Customer Services, and Corporate Management/Representative. However, there was no Customer Service representative, or a designee, at the meetings held in March 2010, November 2010, December 2011, or May 2012. Additionally, there was no Production or Operations representative, or a designee, at the meeting held in December 2011.

The adequacy of your firm’s response cannot be determined at this time. Your firm provided a detailed plan to correct the deficiencies, but it did not provide completion dates or documentation to show that it had implemented the corrective actions.

A follow-up inspection will be required to assure that corrections and/or corrective actions are adequate.

U.S. 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. Additionally, premarket approval applications for Class III devices to which the Quality System regulation deviations are reasonably related will not be approved until the violations have been corrected. Requests for Certificates to Foreign Governments will not be granted until the violations related to the subject devices have been corrected.

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, including 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 action (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. Please provide a translation of documentation not in English to facilitate our review.

Your firm’s response should be sent to: Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Field Operations Branch, White Oak Building 66, Rm 2609, 10903 New Hampshire Ave., Silver Spring, MD 20993. Refer to CMS case #363118 when replying. If you have any questions about the contents of this letter, please contact LaShanda Long, Chief at 301-796-5770.

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 yours,

Steven D. Silverman
Director
Office of Compliance
Center for Devices and Radiological Health