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): **December 19, 2024**

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)	(IRS Employer Identification No.)

1100 Campus Road
Princeton, NJ 08540
(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 (see General Instruction A.2. below):

☐ 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)).

Securities Registered Pursuant to Section12(b) of the Act:

Title of Each Class	**Trading Symbol**	**Name of Exchange on Which Registered**
Common Stock, Par Value $.01 Per Share	IART	Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Events.

On December 19, 2024, a subsidiary of Integra LifeSciences Holdings Corporation (the "Company") received a warning letter from the U.S. Food and Drug Administration (the "FDA").

The warning letter relates to quality system issues identified during FDA inspections at three of the Company's facilities located in Mansfield, Massachusetts, Plainsboro, New Jersey, and Princeton, New Jersey. The warning letter did not identify any new observations that had not already been provided in the Form 483s previously issued to the Company by the FDA at the conclusion of its three inspections in June and August of 2024 (the "2024 Form 483s").

In the 2024 Form 483s, the FDA deemed certain of the Company's devices, including cranial perforators, disposable cottonoid patties, strips, and collagen-based products, to be out of compliance with respect to the quality system regulation. At that time, the Company took a number of voluntary actions including the initiation of shipping holds for several products and a voluntary recall of the disposable patties and strips.

The warning letter does not restrict the Company's ability to manufacture or ship products, require recall of any products, nor restrict the Company's ability to seek FDA 510(k) clearance of products. The warning letter states that premarket approval applications for Class III devices to which the quality system regulation violations are reasonably related will not be approved until the violations have been corrected.

The Company has already submitted several responses to the 2024 Form 483s issued to each of the three manufacturing facilities to the FDA and is in the process of preparing a written response to the warning letter. The Company takes the matters identified in the warning letter very seriously and is committed to working with the FDA to resolve them and continue its comprehensive efforts to remediate the observations. The Company announced in July 2024 that it would initiate a comprehensive compliance master plan, a systematic and holistic approach to improving its quality management system across its manufacturing and supply network.

The Company is not aware of any additional actions stemming from the warning letter that will have a material impact on its previously announced operational or financial expectations and is reaffirming its fourth quarter revenue guidance range of $441 million to $451 million.

The Company cannot give any assurances that the FDA will be satisfied with the Company's response or as to the expected date of the resolution of the matters included in the warning letter. Until the issues cited in the warning letter and 483 observations are resolved to the FDA's satisfaction, additional regulatory action may be taken without further notice.

Forward-Looking Statements

Statements included in this report other than statements of historical fact are forward-looking statements and may be identified by their use of words such as "believe," "may," "might," "could," "will," "aim," "estimate," "continue," "anticipate," "intend," "expect," "plan" and other similar terms. Particularly, our statements regarding our response to the FDA, including those related to the Company's compliance master plan, our ability to resolve the FDA's concerns without a material impact on our financial results, and the impact of any further action by the FDA are forward-looking statements. These forward-looking statements are based on our current assumptions, expectations and estimates of future events and trends. Forward-looking statements are only predictions and are subject to many risks, uncertainties and other factors that may affect our businesses and operations and could cause actual results to differ materially from those predicted. These risks and uncertainties include, but are not limited to, risks related to regulatory approvals, the effects of FDA regulatory requirements, and our ability to address issues raised by FDA inspections adequately and on a timely basis without a resulting recall of product or interruption of manufacturing or shipment of products. Forward-looking statements contained in this Form 8-K should be considered in light of these factors and those factors discussed from time to time in the Company's public reports filed with the Securities and Exchange Commission, such as those discussed under the heading, "Risk Factors," in the Company's most recent annual report on Form 10-K and those discussed in other documents the Company files with or furnishes to the Securities and Exchange Commission. Given these risks and uncertainties, readers are cautioned not to place undue reliance on any forward-looking statements. Forward-looking statements contained in this Form 8-K speak only as of the date of this Form 8-K. These forward-looking statements are made only as the date thereof, and the Company undertakes no obligation to update or revise the forward-looking statements, whether as a result of new information,

future events or otherwise, except as required by law. The provision of the information in this report shall not be deemed an admission as to the materiality of any of the information contained herein.

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: January 6, 2025

By: /s/ Lea Knight
Lea Knight
Title: Executive Vice President and Chief Financial Officer