

**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): **October 19, 2018**

OrthoPediatrics Corp.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

001-38242

(Commission File Number)

26-1761833

(I.R.S. Employer Identification Number)

**2850 Frontier Drive
Warsaw, Indiana**

(Address of principal executive offices)

46582

(Zip Code)

Registrant's telephone number, including area code: **(574) 268-6379**

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 under the Securities Act (17 CFR 230.405) or Rule 12b-2 under the Exchange Act (17 CFR 240.12b-2).

Emerging growth company ☒ [X]

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 ☒ [X]

Item 7.01. Regulation FD Disclosure.

On October 19, 2018, OrthoPediatrics Corp. (“the Company”) issued a press release announcing U.S. Food and Drug Administration (FDA) 510(k) clearance for the RESPONSE 4.5/5.0mm System for treating smaller stature younger patients with complex scoliosis. The system represents the Company’s 26th surgical system and is expected to launch in the fourth quarter of 2018. A copy of the press release is furnished as Exhibit 99.1 to this Current Report.

The Company does not intend for this Item 7.01 or Exhibit 99.1 to be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No. Description

99.1 [Press release issued by OrthoPediatrics Corp. on October 19, 2018.](#)

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SIGNATURE

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.

OrthoPediatrics Corp.

Date: October 19, 2018

By: /s/ Daniel J. Gerritzen
Daniel J. Gerritzen,
General Counsel and Secretary



OrthoPediatrix Corp. Receives FDA 510(k) Clearance for Small Stature Scoliosis System with 26th Surgical System

WARSAW, Indiana, October 19, 2018 — **OrthoPediatrix Corp.** (NASDAQ: KIDS), a company exclusively focused on advancing the field of pediatric orthopedics, announced today it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for its new RESPONSE 4.5/5.0mm System for treating smaller stature younger patients with complex scoliosis. The system represents the Company's 26th surgical system and is expected to launch in the fourth quarter of 2018.

The RESPONSE 4.5/5.0mm System was designed in collaboration with pediatric orthopedic surgeons focused on additional solutions for treating complex pediatric scoliosis patients. It expands the Company's RESPONSE platform to treat smaller stature children and builds upon the successful implant and instrument technology of the RESPONSE 5.5/6.0mm System. The RESPONSE 4.5/5.0mm System offers a hybrid implant technology allowing the option of either a 4.5mm rod in CoCr or 5.0mm rod in titanium or cobalt chromium/chrome material, multiple implant connector options, and innovative, new instrumentation.

OrthoPediatrix' Executive Vice President, David Bailey, stated, "We are pleased with the FDA 510(k) clearance for our 4.5/5.0mm system, which allows physicians to better treat smaller statures and patients at a younger age. Our engineering teams have been diligently working with a prominent group of surgeons, and we are excited to bring their innovative vision to life with another surgical solution for treating complex pediatric scoliosis. The addition of the new system to our scoliosis platform continues to demonstrate OrthoPediatrix' focus and commitment to providing solutions for children with complex spinal disorders."

Scott Luhmann, M.D., Chief of Staff at Shriners Hospital for Children-St. Louis and Associate Professor in the Department of Orthopedic Surgery and Fellowship Director of Pediatric Orthopedic Surgery at Washington University School of Medicine, commented, "The new Response 4.5/5.0mm System brings OrthoPediatrix' expertise and passion for musculoskeletal care of pediatric patients to the area of spinal deformity. This surgeon-centric system is focused on surgical efficacy and efficiency with an elegant rod reduction tool that significantly cuts down laborious task time in the effort to provide optimal patient outcome."

Forward-Looking Statements

This press release includes "forward-looking statements" within the meaning of U.S. federal securities laws. You can identify forward-looking statements by the use of words such as "may," "might," "will," "should," "expect," "plan," "anticipate," "could," "believe," "estimate," "project," "target," "predict," "intend," "future," "goals," "potential," "objective," "would" and other similar expressions. Forward-looking statements involve risks and uncertainties, many of which are beyond OrthoPediatrix' control. Important factors could cause actual results to differ materially from those in the forward-looking statements, including, among others, the risks, uncertainties and factors set forth under "Risk Factors" in OrthoPediatrix' Annual Report on Form 10-K filed with the SEC on March 15, 2018. Forward-looking statements speak only as of the date they are made. OrthoPediatrix assumes no obligation to update forward-looking statements to reflect actual results, subsequent events, or circumstances or other changes affecting such statements except to the extent required by applicable securities laws.

RESPONSE™ Spine System

Designed with a complete focus on children, the RESPONSE system offers a simple, technologically advanced system of instruments and implants to treat the distinct needs of pediatric patients with spinal



deformities. The system features advanced instrument & implant technology including 1) innovative, low profile screw design including a proprietary set screw thread design for improved fixation and reduced potential for cross threading, and 2) unique pedicle screw head accepts a 5.5mm or 6.0mm rod in both cobalt chrome and titanium. Additionally, the system has versatile reduction & de-rotation capabilities with rod reducer instrument designed for easy snap on and off 2-in-1 rod reduction instrument enables each surgeon to perform reduction and de-rotation technique of choice and serves as a rod reducer and de-rotator in one.

About OrthoPediatrics Corp.

Founded in 2006, OrthoPediatrics is an orthopedic company focused exclusively on providing a comprehensive product offering to the pediatric orthopedic market to improve the lives of children with orthopedic conditions. OrthoPediatrics currently markets 25 surgical systems that serve three of the largest categories within the pediatric orthopedic market. This offering spans trauma & deformity, scoliosis, and sports medicine/other procedures. OrthoPediatrics' global sales organization is focused exclusively on pediatric orthopedics and distributes its products in the United States and 38 countries outside the United States.

Investor Contacts

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