

**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 16, 2024**

Nuwellis, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction of Incorporation or
Organization)

001-35312
(Commission File Number)

No. 68-0533453
(I.R.S. Employer Identification No.)

12988 Valley View Road, Eden Prairie, MN
(Address of Principal Executive Offices)

55344
(Zip Code)

(952) 345-4200
(Registrant's Telephone Number, Including Area Code)

Title of each class	Securities registered pursuant to Section 12(b) of the Act:	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	Trading Symbol(s) NUWE	Nasdaq Capital Market

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 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 11, 2024, Nuwellis, Inc. (the “*Company*”) sent a notice to affected customers that it is voluntarily recalling specific lots of the AquaFlexFlow UF 500 Plus extracorporeal blood circuit which is used with the Aquadex Smartflow® or Aquadex FlexFlow® System. The lots are being recalled due to failures of the blood circuit associated with too many mismatch alarms. The blood circuits may indicate “Ultrafiltrate Weight Mismatch” or “Excessive Weight Mismatch” alarms while in use. If not addressed, this failure could result in excess fluid removal from a patient leading to Acute Volume Depletion. As of the date of this Current Report on Form 8-K, the Company is aware of five reported incidences of blood circuit product failures, with three leading to patient dehydration and requiring administration of fluids. The recall is being conducted with the knowledge of the U.S. Food and Drug Administration which has not yet characterized the Class of the recall.

Forward- Looking Statements

This Current Report on Form 8-K contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended and Section 21E of the Exchange Act of 1934, as amended and Private Securities Litigation Reform Act, as amended, including those related to this voluntary recall and any future recall of the AquaFlexFlow UF 500 Plus extracorporeal blood circuit which is used with the Aquadex Smartflow or Aquadex FlexFlow System and any potential adverse events related to the recall(s).

These statements may be identified by the use of forward-looking expressions, including, but not limited to, “expect,” “anticipate,” “intend,” “plan,” “believe,” “estimate,” “potential,” “predict,” “project,” “may,” “should,” “could,” “would” and similar expressions and the negatives of those terms. These statements relate to future events or our financial performance and involve known and unknown risks, uncertainties, and other factors which may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Such factors include those set forth in the Company’s filings with the U.S. Securities and Exchange Commission. Prospective investors are cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date of this Current Report on Form 8-K. The Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

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.

Date: December 16, 2024

NUWELLIS, INC.

By: /s/ NESTOR JARAMILLO, JR

Name: Nestor Jaramillo, Jr.

Title: President and Chief Executive Officer
