4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2026-N-1309]

Revocation of Authorization of Emergency Use of ExThera Medical Corporation Seraph 100 Microbind Affinity Blood Filter (Seraph 100); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of the Emergency Use Authorization (EUA) (the Authorization) issued to ExThera Medical Corporation, for the Seraph 100 Microbind Affinity Blood Filter (Seraph 100). FDA revoked this Authorization under the Federal Food, Drug, and Cosmetic Act (FD&C Act) as requested by the Authorization holder. The revocation, which includes an explanation of the reasons for revocation, is reprinted at the end of this document.

DATES: The revocation of the Authorization for the ExThera Medical Corporation Seraph 100 Microbind Affinity Blood Filter (Seraph 100) is effective as of November 24, 2025.

ADDRESSES: Submit written requests for a single copy of the revocation to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5441, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request or include a Fax number to which the revocation may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the revocation.

FOR FURTHER INFORMATION CONTACT: Michael Hoffman, Office of Product Evaluation and Quality, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm.2410, Silver Spring, MD 20993-0002, 301-796-6476 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb-3) as amended by the Project BioShield Act of 2004 (Pub. L. 108-276) and the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (Pub. L. 113-5) allows FDA to strengthen the public health protections against biological, chemical, radiological, or nuclear agent or agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations.

On April 17, 2020, FDA issued the Authorization to ExThera Medical Corporation, for the Seraph 100 Microbind Affinity Blood Filter (Seraph 100), subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the *Federal Register* on July 14, 2020 (85 FR 42407), as required by section 564(h)(1) of the FD&C Act. Subsequent updates to the Authorization were made available on FDA's website.

The authorization of a device for emergency use under section 564 of the FD&C Act may, pursuant to section 564(g)(2) of the FD&C Act, be revoked when the criteria under section 564(c) of the FD&C Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the FD&C Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the FD&C Act).

II. Authorization Revocation Request

In a request received by FDA on October 21, 2025, ExThera Medical Corporation, requested the withdrawal of, and on November 24, 2025, FDA revoked, the Authorization for the ExThera Medical Corporation's Seraph 100 Microbind Affinity Blood Filter (Seraph 100). ExThera Medical Corporation notified FDA that as of the date of this revocation, no viable Seraph 100 Microbind Affinity Blood Filter (Seraph 100) remained under EUA distribution and requested FDA withdraw the ExThera Medical Corporation's Seraph 100 Microbind Affinity

Blood Filter (Seraph 100). FDA has determined that it is appropriate to protect the public health or safety to revoke this Authorization.

III. Electronic Access

An electronic version of this document and the full text of the revocation is available on the internet at https://www.regulations.gov/.

IV. The Revocation

Having concluded that the criteria for revocation of the Authorization under section 564(g)(2)(C) of the FD&C Act are met, FDA has revoked the EUA of ExThera Medical Corporation's Seraph 100 Microbind Affinity Blood Filter (Seraph 100). The revocation in its entirety follows and provides an explanation of the reasons for revocation, as required by section 564(h)(1) of the FD&C Act.

November 24, 2025

Ann Vu, JD, RAC
Chief of Staff
ExThera Medical Corporation
757 Arnold Drive Suite B
Martinez, CA 94553 USA

Re: Revocation of EUA200165

Dear Ann Vu,

This letter is in response to the request from ExThera Medical Corporation (ExThera), in an email dated October 21, 2025, that the U.S. Food and Drug Administration (FDA) formally withdraw the Emergency Use Authorization (EUA200165) issued on April 17, 2020, for the Seraph 100 Microbind Affinity Blood Filter (Seraph 100). We are considering your request a request to revoke this EUA. FDA understands that, as of the date of this letter, there remains no viable Seraph 100 device distributed under the EUA in distribution in the United States. The distribution permitted under the Investigational Device Exemption Expanded Access program of Seraph 100 or Oncobind devices is not affected by the requested revocation.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because ExThera has requested that FDA revoke the EUA for the Seraph 100, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA200165 for the Seraph 100 Microbind Affinity Blood Filter, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Seraph 100 Microbind Affinity Blood Filter is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register,* pursuant to section 564(h)(1) of the Act.

Sincerely,

Ellen J. Flannery -S

Digitally signed by Ellen J. Flannery -S
Date: 2025.11.24 12:55:50 -05'00'

Ellen J. Flannery, J.D.
Deputy Center Director for Policy
Director, Office of Policy
Center for Devices and Radiological Health
Food and Drug Administration

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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