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,

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