June 30, 2021

Ms. Carolyn Shelton
VP, Global Regulatory & Medical Affairs, Product Stewardship
Advanced Sterilization Products, Inc.
6920 Seaway Blvd.
Everett, WA 98203

Re: Revocation of EUA

Dear Ms. Shelton:

This letter is in response to Advanced Sterilization Products, Inc. (ASP) STERRAD's request dated June 4, 2021, that the U.S. Food and Drug Administration (FDA) withdraw the Emergency Use Authorization (EUA) for the ASP STERRAD 100S, NX, and 100NX Sterilization Systems (hereafter referred to as "ASP STERRAD Decontamination Systems") issued on April 11, 2020, and revised and reissued on June 6, 2020, and January 21, 2021. ASP STERRAD will no longer make the ASP STERRAD Decontamination Systems available for the authorized emergency use. In its request, ASP STERRAD confirmed that it has ceased operation of all ASP STERRAD Decontamination Systems sites as well as associated activities.

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 be revoked when the circumstances described under section 564(b)(1) of the Act no longer exist (section 564(g)(2)(A) of the Act), the criteria under section 564(c) of the Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because ASP STERRAD has notified FDA that it has ceased operations and associated activities and requests withdrawal of the authorization, and consistent with FDA's belief that the known and potential benefits of these systems, when used for their emergency use, no longer outweigh the known and potential risks of such use, FDA has determined that it is appropriate to revoke this authorization because the criteria for issuance of an EUA under section 564(c)(2)(B) of the Act are no longer met. Moreover, based on the same information, FDA has concluded under section 564(g)(2)(C) of the Act that other circumstances make revocation of this EUA appropriate to protect the public health or safety.

Accordingly, FDA hereby revokes ASP STERRAD's EUA for the ASP STERRAD Decontamination Systems, pursuant to sections 564(g)(2)(B) and 564(g)(2)(C) of the Act. As of the date of this letter, the ASP STERRAD Decontamination Systems are no longer authorized for emergency use by FDA.

FDA encourages ASP STERRAD to inform its customers of this revocation.

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

Sincerely,

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration