



August 23, 2022

Brooke McCutchan, MT(ASCP)  
Talis Biomedical Corporation  
3400 Bridge Pkwy  
Redwood City, CA 94065

**Re: Revocation of EUA210502**

Dear Brooke McCutchan:

This letter is in response to a request from Talis Biomedical Corporation, received August 12, 2022, that the U.S. Food and Drug Administration (FDA) revoke the Talis One COVID-19 Test System – EUA210502 issued on November 5, 2021. The Talis One COVID-19 Test System has not been commercially distributed by Talis Biomedical Corporation in the U.S.

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. Because Talis Biomedical Corporation notified FDA that Talis Biomedical Corporation has not commercially distributed the authorized product in the U.S. and requested FDA revoke the authorization of the Talis One COVID-19 Test System, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, pursuant to section 564(g)(2)(C) of the Act, FDA revokes EUA210502. As of the date of this letter, the Talis One COVID-19 Test System 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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Namandjé N. Bumpus, Ph.D.  
Chief Scientist  
Food and Drug Administration