May 9, 2023

Kambiz Tajkarimi

(b) (6)

Sent via email: (b) (6)

Re: Docket Number FDA-2020-P-1864

Dear Dr. Tajkarimi:

This letter is a final response to your citizen petition, dated September 11, 2020, requesting that the Food and Drug Administration (FDA) "refrain from granting a 510(k) clearance or any other premarket clearance or approval to the Augmenta silicone penile implant." Your petition was received and processed under 21 CFR 10.30. FDA sent you an acknowledgement letter on September 14, 2020, and an interim response on May 17, 2021. As explained below, your petition is dismissed as moot in part and denied in part.

I. Actions Requested

Your petition alleges the design of the Augmenta silicone penile implant (the implant or the device) is "flawed and unsafe." Specifically, you state that the "mesh tabs specifically along the sides of the implant, which are intended to attach to the lateral edges of the corpora of the penis, will constrict the corpora and its ability to fluctuate between a flaccid and erect state." Your petition sets forth your belief that "these mesh tabs will form adhesions, scar tissue, constriction of the corpora, penile deformities, and possible perforation of the corpora and/or penile skin given their placement . . . and will likely cause harm to patients." You also allege in your petition that Augmenta has a "track record of disregarding FDA regulations, including false and misleading advertising" and allege that Augmenta published an Informed Consent document that indicated the device was "approved" by the FDA before it received clearance. While the action requested identified in your petition is that FDA "refrain from granting a 510(k) clearance or any other premarket clearance or approval to the Augmenta silicone penile implant," FDA interprets these additional allegations as a request for the agency to initiate enforcement action. In accordance with 21 CFR 10.30(e) and for the reasons discussed below, your request that FDA refrain from granting any clearance or approval for the implant is dismissed as moot and your request that FDA initiate enforcement action against Augmenta is denied for falling outside the scope of relief that can be granted in a citizen petition.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903
www.fda.gov

II. Request to Refrain from Clearing the Device

On September 30, 2022, FDA cleared Augmenta's premarket notification (510(k)) for the Augmenta Penile Implant.[1] A 510(k) is a premarket submission made to FDA to demonstrate that a new device is "substantially equivalent" to a legally marketed device. A device is substantially equivalent if, in comparison to a predicate it:

- (1) has the same intended use as the predicate and has the same technological characteristics as the predicate; or
- (2) has the same intended use as the predicate; and
- has different technological characteristics and does not raise different questions of safety and effectiveness than the predicate; and
- the information submitted to FDA demonstrates that the device is as safe and effective as the legally marketed device.

The type of data and information necessary to establish substantial equivalence varies by the type of device and the differences between the new device and the predicate device.[2] FDA makes these determinations based on evidence and information provided by the applicant. Notably, the cleared device does not include the mesh tabs that formed the basis of your concern.[3] Moreover, the review team determined that the device was substantially equivalent to the predicate[4] and any differences did not raise new issues of safety or effectiveness. See section 513(i) of the Federal Food, Drug, and Cosmetic Act. Therefore, FDA is dismissing your request to "refrain from granting a 510(k) clearance" as moot.

III. Request to Initiate Enforcement Action

As noted above you also make multiple allegations regarding possible violations committed by Augmenta in your petition. Requests for FDA to initiate enforcement actions are not within the scope of our citizen petition regulations. See 21 CFR 10.30(k). Such matters are within the discretion of the agency. As a result, this request is denied. FDA appreciates the information that you provided. We take complaints seriously, and we will evaluate this matter to determine what follow-up action, if any, is appropriate. Decisions with respect to initiating enforcement actions are generally made on a case-by-case basis.

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[1] 510(k) summary for Augmenta Penile Implant (K200073), Sept. 30, 2022, *available at* https://www.accessdata.fda.gov/cdrh_docs/pdf20/K200073.pdf.
[2] The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)], Guidance for Industry and Food and Drug Administration Staff, July 28, 2014, *available at* https://www.fda.gov/media/82395/download.
[3] *See* 510(k) summary for Augmenta Penile Implant (K200073), Table 2: Comparison with Predicate Device.
[4] Substantial equivalence letter from FDA to Augmenta LLC regarding K200073, *available at* https://www.accessdata.fda.gov/cdrh_docs/pdf20/K200073.pdf.

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If you have any questions about this response, please contact Daniel Schieffer in our Office of Policy at daniel.schieffer@fda.hhs.gov or 301-796-3350.

Sincerely,

Ellen J. Flannery -S

Digitally signed by Ellen J. Flannery -S
Date: 2023.05.09 10:10:20 -04'00'

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

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