May 17, 2021

Kambiz Tajkarimi
(b) (6)

Sent via email: (b) (6)

Re: Docket Number FDA-2020-P-1864

Dear Dr. Tajkarimi:

This is an interim response to the petition dated September 11, 2020 and filed by the Food and Drug Administration (FDA) on the same day. In the petition, you requested FDA "refrain from granting a 510(k) clearance or any premarket clearance or approval to the Augmenta silicone penile implant."

FDA has been unable to reach a decision on your petition because it raises issues requiring further review and analysis by agency officials. This interim response is provided in accordance with FDA regulations on citizen's petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

If you have any questions about this interim response, please contact Karen Fikes of our Office of Policy Staff at (301) 796-9603.

Sincerely,

Ellen J. Flannery -S
Digitally signed by Ellen J. Flannery -S
Date: 2021.05.17 15:45:57 -04'00'

Ellen J. Flannery, JD
Deputy Center Director for Policy,
Director, Office of Policy
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