Citizen Petition

September 11, 2020

The undersigned submits this petition under 21 CFR part 10 of the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act to request the Commissioner of Food and Drugs ("Commissioner") to refrain from granting a 510(k) clearance or any premarket clearance or approval to the Augmenta silicone penile implant.

A. Action Requested

The undersigned request that the Commissioner refrain from granting a 510(k) clearance or any other premarket clearance or approval to the Augmenta silicone penile implant.

B. Statement of Grounds

My name is Kambiz Tajkarimi, MD, and I am Board-certified prosthetic urologist based in Northern Virginia. I am one of the highest volume implanters in the country, and I have a strong track record of patient safety and satisfaction. I also manufacture and distribute several medical devices and am therefore proficient in FDA regulations. I am a physician customer of International Medical Devices (IMD)'s penile silicone implant. I do not have a financial interest in IMD.

It is my understanding that Augmenta, LLC recently filed a 510(k) clearance for a cosmetic silicone penile implant. I further understand that the design of the implant is based on trade secrets from IMD during a visit by Dr. Robert Cornell, Augmenta's founder, to IMD's facility under a Non-Disclosure Agreement. As a result, the Augmenta implant is the subject of pending litigation against Augmenta and its founder, Dr. Robert Cornell and others, captioned *International Medical Devices, Inc., et al. v. Robert Cornell, MD, et al.* (California Central District Case No. 2:20-cv-03503-CBM (RAOx)) (the "Litigation"). In the complaint, IMD alleges claims for theft of IMD's trade secrets, breach of contract (a non-disclosure agreement), and other offenses. IMD is currently pursuing a preliminary injunction in this action to prevent further damages.

I believe Augmenta has engaged in several actions that justify the request made in this Citizen Petition. These actions, which are explained below, include design flaws in the Augmenta implant that have a high likelihood of causing public harm based on subject matter expert assessment and Augmenta's track record of disregarding FDA regulations, including false and misleading advertising.

Design Flaws of Augmenta Implant

I believe the fundamental design of the Augmenta implant is flawed and unsafe. I have analyzed publicly available, detailed photos of the implant and shared them with professors of urology and experts with the Society of Sexual Medicine and the American Urological Association.

Our assessment has been unanimous 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. Accordingly, we believe 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. This is unprecedented for any type of penile implant (and possibly, more generally, any silicone implant) and will likely cause harm to patients.

It is important that the FDA consider this perspective on this critical issue.

Augmenta's Disregard for FDA Regulations

I understand that Augmenta unfortunately has a history of disregarding FDA regulations and thus compromising public safety. As alleged in IMD's Litigation, Augmenta has advertised and promoted its implant on various Augmenta-owned websites and social media accounts without any apparent FDA clearance or approval. Augmenta has also attempted to sell its implant online with price lists and an online marketplace despite having no apparent FDA clearance. Furthermore, Augmenta has made and continues to make claims that the implant is "safe and effective" absent any apparent FDA clearance or approval. All of these activities appear to violate 21 C.F.R. § 812.7, among other federal regulations.

Moreover, Augmenta published an Informed Consent document online that falsely claims that, "[i]n December, 2019, the Augmenta subcutaneous silicone penile implant was approved by the United States Food and Drug Administration (FDA) for use in penile augmentation and reconstruction." IMD asserts this is a false and misleading statement.

I have consulted with several patients who have met with Augmenta physicians, including Dr. Robert Cornell, and appear to have been offered the Augmenta implant by those physicians. I am happy to provide further information (in a compliant manner) on these patient experiences with Augmenta.

C. Environmental Impact

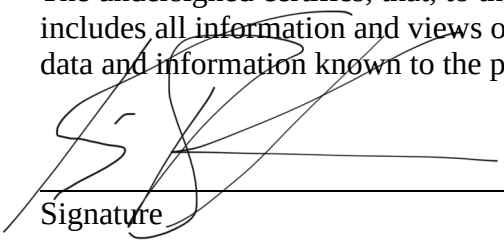
We claim categorical exclusion under 25.30, 25.31, 25.32, 25.33, or 25.34 of this chapter or an environmental assessment under 25.40 of this chapter.

D. Economic Impact

Economic impact information will be submitted upon request of the Commissioner.

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.



Signature

Kambiz Tajkarimi, MD
Name of petitioner

(b) (6)
Mailing address

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Telephone number