DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

September 14, 2020

Kambiz Tajkarimi
(b) (6) [redacted]

Sent via email: (b) (6) [redacted]

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting that FDA refrain from granting a 510(k) clearance or any other premarket clearance or approval to the Augmenta penile implant was received by this office on 09/11/2020.

It was assigned docket number FDA-2020-P-1864. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter and in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,
Dynna Gorham-bigby -S
Digitally signed by Dynna Gorham-bigby -S
Date: 2020.09.14 12:26:48 -04'00'
Dynna Bigby
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)