U.S. FOOD & DRUG ADMINISTRATION

May 30, 2020

Reginald Burgess
% Garrett Skelly, Esq.
160 Centennial Way, Suite 21
Tustin, California 92780

Re: Citizen Petition – for Reconsideration of ruling FDA-2013-P-0949-0005 – Docket Number FDA-2013-P-0949

Dear Mr. Burgess:

This letter responds to the above-referenced reconsideration petition dated April 2, 2014, that you submitted to the Food and Drug Administration (FDA) (Reconsideration Petition). Your Reconsideration Petition requests that FDA reconsider its response dated March 21, 2014 (FDA Response), to your petition dated August 6, 2013 (Citizen Petition), in which FDA denied your requests to amend the clearance of Otto Bock C-LEG (3C100), submitted under 510(k) premarket notification K991590 as per the limitations of exemption in Title 21 of the Code of Federal Regulations (CFR) 890.9, to include both "prescription" and "over the counter use" and to label all external prosthetic devices regulated under 21 CFR 890.3420 and 890.3500 for over-the-counter use. In addition, you allege that Otto Bock "fraudulently submitted its 510K request."

As outlined below, in accordance with 21 CFR 10.33(i) and 10.30(e), FDA (1) reaffirms its denial of the requests contained in your Citizen Petition, because your Reconsideration Petition fails to raise new issues that justify FDA reaching a different conclusion, and (2) denies your additional request to revoke the clearance of K991590, because the claim that the device has different technological characteristics is a new issue raised and is thus outside the scope of reconsideration.

A. Amending K991590 and all external prosthetic devices

As stated in the FDA Response, K991590 was cleared for marketing with indications for prescription use only[1] and with labeling that included the prescription use statement.[2] Under 21 CFR 890.9, a 510(k) submission is required for a request to add "over-the-counter use" to the indications for use of a device that was previously for "prescription use only." Thus, labeling these devices for over-the-counter use is a change to the indications for use of the device and must be submitted as part of a premarket notification (510(k)) by the owner or operator of the establishment that has the rights to manufacture and/or distribute the device. Given this requirement, the Agency previously informed you that it cannot consider your request through a citizen petition. Your Reconsideration Petition does not provide any information that would alter FDA's analysis. FDA, therefore, denies this request in your Reconsideration Petition for the reasons stated in the FDA Response.

[1] http://www.accessdata.fda.gov/cdrh_docs/pdf/K991590.pdf
[2] 21 CFR 801.109(b)(1)

B. Prescription Use Restriction

The statement of grounds in your Reconsideration Petition indicated that the FDA Response "focuses on a non-existent 21 CFR 801.109(b)(1) requirement in order K991590." Although 21 CFR 801.109(b)(1) is not stated in the 510(k) Summary for K991590, the submission was cleared for marketing with indications for prescription use only and with labeling that included the prescription use statement. You further indicate that, even if prescription use only applies for the C-LEG (3C100), Otto Bock is misbranding and selling the device in violation of 21 CFR 801.109(a) and (b) because prosthetists "are 'lay-people' and are not 'licensed by law'." We are not aware of reports that the C-LEG (3C100) is directly prescribed by prosthetists, nor does your Reconsideration Petition provide evidence of such. Certified prosthetists are trained to provide the help necessary to fit the prosthetic device and work to fulfill the physician's prescription for safe operation of a prosthetic device. The surgeon, prosthetist and patient all meet together to ensure the best care for the patient. Prosthetists are certified by a credentialing body such as the American Board for Certification in Orthotics, Prosthetics and Pedorthics, Inc. (ABC). The prosthetist designs the prosthesis and selects its components, makes and fits the prosthesis, provides instruction on how to use and care for it, and also provides repairs and adjustments to it over time, but does not prescribe its use.

The petition further argues that this "prescription" requirement has an effect on the "Prohibition of discrimination by public accommodations" under the Americans with Disabilities Act (ADA), 42 USC 12182. FDA is charged with reviewing and determining when a device should be available only by prescription (see section 520(e) of the Federal Food, Drug, and Cosmetic Act). Medical device manufacturers are responsible for ensuring the continued safety of their devices, and some choose to limit who may repair their devices. FDA does not control these manufacturers' decisions concerning who may repair their devices. Moreover, the ADA, which is not part of the FD&C Act, is not relevant to the question of whether FDA should designate a device as "prescription use only," a determination that FDA makes pursuant to its authority under the FD&C Act. Therefore, in determining that issue under the FD&C Act, FDA does not and cannot address any alleged ADA-related discrimination in the sales and services of Otto Bock C-LEG (3C100).

C. Revoking Pre-market Clearance of C-LEG 3C100

Your Reconsideration Petition request to revoke the premarket clearance of Otto Bock C-LEG (3C100), allegedly because Otto Bock fraudulently submitted its 510(k) submission and the device operates by different scientific technology than the legally marketed device, is outside the scope of reconsideration as reconsideration is based on the administrative record of the prior Citizen Petition decision and this issue was not considered previously and thus was not part of the relevant administrative record.

D. Amending 820.198 and 820.200 to require manufacturers to provide self-service information and resell parts.

In the "Statement of grounds" in your Reconsideration Petition, you provide information related to your prior petition to the FDA, FDA-2013-P-1080, for amending 21 CFR 820.198 and 820.200 to require manufacturers to provide self-service information and resell parts. Please refer to the response dated June 02, 2014, for the Agency's position on this matter. Please note that both prescription and over-the-counter medical devices are subject to 21 CFR Part 820, as applicable. Designation as an over-the-counter device does not impact the manufacturer's user support requirements including the ability to dictate how software, parts, and service information be shared with the end-user.

E. Conclusion

For the reasons discussed above, in accordance with 21 CFR 10.33(i) and 10.30(e), FDA reaffirms the FDA Response and denies your additional request.

If you have any questions, please contact Mr. Madhusoodana Nambiar by e-mail at madhusoodana.nambiar@fda.hhs.gov or 301-796-5837.

Sincerely,

Ellen J. Flannery -S

Digitally signed by Ellen J. Flannery -S
Date: 2020.05.30 19:28:44 -04'00'

Ellen J. Flannery, J.D.
Deputy Center Director for Policy
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