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ORIGINAL

April 2, 2014 USPS article 9405 9036 9930 0157 9320 15

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room. 1061
Rockville, MD 20852

Re: C-leg wearer
Reginald Burgess
(b) (6) [redacted]

RECONSIDERATION PETITION TO AMEND EXTERNAL PROSTHETIC ORDER AND PROCEDURES AND CLASSIFICATION OF ALL EXTERNAL PROSTHETIC DEVICES IN 21 CFR 890.3420 AND 21 CFR 890.3500 TO READ AS BOTH "PRESCRIPTION" AND "OVER THE COUNTER USE" IN PARTICULAR FIRST AND FOREMOST FOR THE C-LEG - K991590.pdf

Citizen Petition – for Reconsideration of ruling FDA-2013-P-0949-0004

The undersigned submits this petition for reconsideration under 21 CFR 10.33 as to 21 CFR 801.109; 21 CFR 890.3420, 21 CFR 890.3500 and 21 CFR 820.198 (Federal Food, Drug, and Cosmetic Act or the Public Health Service Act or any other statutory provision for which authority has been delegated to the Commissioner of Food and Drugs under 21 CFR 5.10) to request the Commissioner of Food and Drugs to amend an order

RE: Complaint - C-Leg product under 21 CFR 820.198, unsafe operation & Violation of: The Consumer Legal Remedies Act, Cal. Civ. Code 1750
http://www.regulations.gov/#!documentDetail;D=FDA-2013-P-0949-0004

A. Decision Involved

The ruling authored March 21, 2014 and issued and posted March 27, 2014 to the docket and mailed same day of FDA-2013-P-0949 as docket item 4 at http://www.regulations.gov/#!documentDetail;D=FDA-2013-P-0949-0004

FDA-2013-P-0949

2014-3044

CP

Requesting the Commissioner amend the approval order K991590.pdf at http://www.accessdata.fda.gov/cdrh_docs/pdf/k991590.pdf to include "OVER THE COUNTER USE " in addition to "PRESCRIPTION" at the final page.

B. Action Requested

The Commissioner MUST amend this order OR in the alternative REVOKE said order as per ". . . the limitations of exemptions in 21 CFR 890.9 state that a 510(k) is required if " ". . . (b) The modified device operates using a different fundamental scientific technology than a legally marketed device in that generic type of device..." The device at K991950 is modeled upon a device that is SAFE at all times found originally in U.S. Patent which the C-leg allegedly is based[1], which came to be known as "Mauch" hydraulics and/or "Mauch Knee" as set forth in US Patent US Patent 2,561,370[2] from July 24, 1951, and now called simply the Stance And Support knee – abbreviated "SNS", but as the petition shows, a 3C100 is an electro-mechanically operated quasi-hydraulic device that will FAIL when power fails and thus "operates using a different fundamental scientific technology than a legally marketed device in that generic type of device"

C. Statement of grounds

The ruling authored by Nancy K. Stade bears several errors in viewing the petition. It focuses on a non-existent 21 CFR 801.109(b)(1) requirement in order K991950. Even if this were "discretionarily viewed" as what the "x" behind the

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[1] The Otto Bock designation for their non-microprocessor Mauch Knee type product is the "3C1" used for the 510K submission for a pre 1976 device

[2] http://pdfpiw.uspto.gov/.piw?Docid=02561370&homeurl=http%3A%2F%2Fpatft.uspto.gov%2Fnetacgi%2Fnph-Parser%3FSect1%3DPTO1%2526Sect2%3DHITOFF%2526d%3DPALL%2526p%3D1%2526u%3D%25252Fnetahtml%25252FPTO%25252Fsrchnum.htm%2526r%3D1%2526f%3DG%2526l%3D50%2526s1%3D2,561,370.PN.%2526OS%3DPN%2F2,561,370%2526RS%3DPN%2F2,561,370&PageNum=&Rtype=&SectionNum=&idkey=NONE&Input=View+first+page

word prescription means, then STILL Otto Bock is in violation of the Act and is mis-branding and selling in violation of 21 CFR 801.109 – as section "(a)" and "(b)" BOTH apply . IF a "prescription only use" did apply then "(a)" is not met.

(b) The label of the device, other than surgical instruments, bears:

(1) The statement "Caution: Federal law restricts this device to sale by or on the order of a ____", the blank to be filled with the word "physician", "dentist", "veterinarian", or with the descriptive designation of any other practitioner licensed by the law of the State in which he practices to use or order the use of the device; and

Prostheticists are "lay-people" and are not "licensed by law". They "purchase" a certification which means nothing as it relates to medical science.

The petition further argues the effect of this "prescription" requirement against the Americans with Disabilities Act section 42 USC 12182 and the ruling touches nowhere there; BUT does extend itself beyond what the K991950 order actually says especially in relation to other orders which DO specifically mention the 21 CFR 801.109 requirement. See attachments A and B. No such reference is in found in K991950 and in fact the opposite is found – that the device is exempt because it has the same criteria as a similar device on the market prior to 1976.

Not true – as shown above and in the petition.

Further, the petition seeks the Commissioner "AMEND" the order under 21 CFR 820.198 (and 200) to allow sale of parts ONCE THE ITEM HAS BEEN SOLD.

Certainly repairs and maintenance does not require a "prescription" - as this amounts to a form of discrimination and extortion in violation to 42 USC 12182.

Finally the basis of the ruling is that a citizen petition cannot be used to request a "510K submission"; and this is simply NOT true. A citizen petition can be used to

alert the Commissioner to fraud and then the Commissioner MUST ORDER a new 510 K submission to address the issues of fraud and mis-branding under 21 USC 331 raised as the petition so does. In no way does the 3-C100 operate like the 3C1 – as claimed and in fact is more dangerous depending on battery power.

Pursuant to 21 FR 10.33(d)

(1) The petition demonstrates that relevant information or views contained in the administrative record were not previously or not adequately considered.

This is because Otto Bock clearly fraudulently submitted its 510K request because the device the subject of K991950 DOES NOT operate as a "Mauch" cylinder unit and IS an electro-mechanically operated quasi-hydraulic device that will FAIL when power fails and thus "***operates using a different fundamental scientific technology than a legally marketed device in that generic type of device***". Otto Bock has hidden this is its "prescription use only" requirement locking in a user to come to them for every single thing for service and support so the truth of the device could not be discovered by distributors, competitors or physicians, and other medical [or repair] professionals who would order the use of the device – who frankly would never do so if the truth was known.

A 510K submission in fraud is "mis-branding" under 21 USC 331 at the highest level. The C-Leg – under K991950 is actually thus a Class III device.

Of course for Otto Bock to admit the dangers of using the device would find the item not feasible to market – so they hid the truth. Otto Bock twisted the facts and truth to suit their pocket book. Other devices on the market – for instance the Endolite "Smart Adaptive"[3] is truly hydraulic stance and support even with the battery power removed and this citizen has tested such. Others disclose this power required flaw as an electro-mechanical quasi-hydraulic device. See also

[3] The Endolite – Blatchford "Smart Adaptive" is a pneumatic swing, hydraulic stance and support hybrid

http://www.fda.gov/%20MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/default.htm

Thus a pre-market approval submitted in FRAUD must be revoked.

(2) The petitioner's position is not frivolous and is being pursued in good faith.

The initial petition was clear on the lengths an owners must go to obtain service and a second petition is pending as FDA-2013-P-1080-0001 found at http://www.regulations.gov/#!documentDetail;D=FDA-2013-P-1080-0001 as to amend 21 CFR 820. 198 and 200 to allow owners to get service even if and after the original sale is made. It must be noted that the ruling nor regs does not speak to any re-sale of the item and indeed speaks to the fact that public policy found at 42 USC 12182 (the ADA) instead is being violated.

(3) The petitioner has demonstrated sound public policy grounds supporting reconsideration.

Here, the Commissioner has a duty to weight the practical effect of the "prescription" only use box "checked" against what 42 USC 12182 dictates to persons with disabilities who must depend on these kinds of devices. Nowhere does Otto Bock warn the buyer they will not be able to get service AFTER 5 years, and nowhere is it revealed the C-Leg 3-100 and its progenies all depend on battery power or will loose ALL support unexpectedly. This is mis-branding and a violation of the American with Disabilities Act (ADA) which the Commissioner has a duty to consider that over-rules the aspect of "WHO" may submit a "510K" request. The will of Congress trumps the interpretation to turn a blind eye to the violation of law and public policy. The Commissioner has a duty to adjust the regulations to comply with the ADA

(4) Reconsideration is not outweighed by public health or other public interests.

The fact is only a wearer can know if the item is safe. Otto Bock authored a self-serving study which nowhere in it does it warn that the C-leg is a completely powered electro-mechanical quasi-hydraulic leg attached and also found at http://www.ottobock.com/cps/rde/xbcr/ob_com_en/646B33-GB-01-1003w.pdf

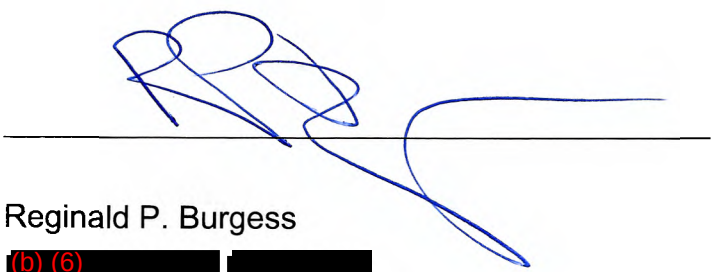
Attached as Attachment C

For Otto bock to then REFUSE to allow an owner to service their OWN leg by providing instructions for even a simple battery replacement and then support software to re-program the item inexcusable.

The ***sale of an item is complete ownership*** – not a lease – and the software and service information must be included to not be fraud.

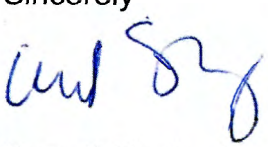
For the Commissioner to ignore this reality as it relates to the general – wearing as amputee - public is equally inexcusable.

To allow Otto Bock to continue what is certainly a conspiracy to defraud the government and wearers is beyond inexcusable to incredulous. As an over the counter item Otto Bock would be required to provide user support.



Reginald P. Burgess
(b) (6) [redacted]
[redacted]
[redacted]

Sincerely



Garrett Skelly, Attorney for Reginald Burgess

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