Argo Medical Technologies Inc. 9/30/15

Department of Health and Human Services

Public Health Service
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

WARNING LETTER

SEP 30, 2015

VIA UNITED PARCEL SERVICE

John V. Hamilton
Vice President, Regulatory
Argo Medical Technologies, Inc.
33 Locke Dr., Suite 240
Marlborough, MA 01752

Dear Mr. Hamilton:

The Food and Drug Administration (FDA) authorized marketing of the ReWalk deviceunder a de novo classification (K131798/DEN130034) on June 26, 2014. On that same day, FDA ordered Argo Medical Technologies, Inc. (Argo) to conduct post-market surveillance of the ReWalk device, in accordance with section 522 of the Federal Food, Drug and Cosmetic Act (the Act), 21 U.S.C. § 360l, and Title 21 of the Code of Federal Regulations (CFR) Part 822.

FDA issued this order (PS140001) (the "522 Order") because the device's failure to prevent a fall would be reasonably likely to cause serious user injury and/or death through fall related sequelae, such as traumatic brain injury (TBI), spinal cord injury

(SCI), and fractures to the user. In addition, an individual assisting the user could also be placed at risk of harm from a potential fall.

Argo's proposed 522 post-market surveillance (PS) study plan synopsis was received by FDA on July 31, 2014. FDA reviewed the PS study plan synopsis and informed you in a letter dated September 29, 2014 that Argo's submission lacked the information needed to complete the review. FDA listed the deficiencies with your firm's submission and required a complete response within 30 days, but the Agency did not receive a response from your firm within 30 days.

On November 5, 2014, FDA notified you that your firm's response was overdue. FDA then received a letter from you dated November 6, 2014 enclosing a PS study plan (PS140001/A001). FDA reviewed the PS study plan and, in a letter dated February 13, 2015, informed you that Argo's submission dated November 6, 2014 also lacked the information needed to complete the review. FDA listed the deficiencies with your firm's submission and required a complete response within 30 days, but the Agency did not receive a response from your firm within 30 days.

On March 16, 2015, FDA notified you via email that Argo's response to FDA's February 13, 2015 letter was overdue and asked when your firm would provide its response. On March 20, 2015, you responded via email to FDA and stated that the response would be submitted by April 15, 2015. However, FDA did not receive a response by April 15, 2015.

On April 16, 2015, FDA again requested a status update on the overdue Argo response to FDA's February 13, 2015 letter. On May 22, 2015, Argo replied to FDA stating that it was in a position to respond on all but one issue and asked to discuss that issue with FDA staff before submitting the formal response. FDA attempted multiple times [via phone and email], from June 12, 2015 to July 28, 2015, to coordinate the requested teleconference with your firm in an attempt to resolve the outstanding issues. FDA also notified you in an email dated June 24, 2015 that the Agency considered Argo's 522 study to be out of compliance.

Argo did not reply to FDA's request for proposed teleconference dates until July 29, 2015. In your July 29, 2015 email, you stated that your firm would have proposed dates for the teleconference by the week of August 3, 2015. However, on August 10, 2015, Argo notified FDA for the first time that it was proposing substantial changes to the methods and study plan (PS140001/A001) and requested an in-person meeting with FDA if the Agency had any questions regarding these major proposed changes.

After reviewing the proposals in Argo's August 10, 2015 letter, FDA provided feedback to you on September 2, 2015 and recommended that your firm submit a revised PS study plan addressing this feedback and the deficiencies identified in the

Agency's February 13, 2015 letter as soon as possible. To date, FDA has received no response to this communication from your firm, Argo has not submitted a revised study plan, and there has been a substantial lack of progress towards commencement of the 522 PS study required under the 522 Order.

Further, as stated within the 522 Order, a manufacturer must commence surveillance under section 522 of the Act not later than 15 months after the day on which an order is issued under section 522 (see section 522(b) of the Act). The 15-month time frame within which Argo's PS study plan must be approved and its study must be commenced closed on September 28, 2015.

Failure or refusal of a manufacturer to comply with requirements under section 522 of the Act, which includes requirements specified under 21 CFR Part 822, is a prohibited act under section 301(q)(1)(C) of the Act, 21 U.S.C. § 331(q)(1)(C). Further, failure or refusal to comply with a requirement under section 522 of the Act renders a device misbranded under section 502(t)(3) of the Act, 21 U.S.C. § 352(t)(3).

Argo Medical Technologies, Inc. has:

- failed to submit a revised PS study plan that adequately addresses the deficiencies described in FDA's September 29, 2014 letter, as well as those deficiencies described in FDA's February 13, 2015 letter (see 21 CFR 822.19);
- failed to design a PS study plan that answers the questions identified in the 522 Order (see 21 CFR 822.11);
- failed to have an approved PS study plan (see 21 CFR 822.20); and
- failed to commence surveillance under section 522 of the Act not later than 15 months after the day on which the 522 Order was issued (see section 522(b) of the Act).

Therefore, Argo has committed a prohibited act under section 301(q)(1)(C) of the Act by failing to comply with requirements under section 522 of the Act. Your firm's ReWalk device, authorized for marketing under de novo classification (K131798/DEN130034), is currently misbranded under section 502(t)(3) of the Act.

You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil money penalties. Please note that Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

Within fifteen (15) calendar days from the date you receive this letter, please submit your firm's section 522 post-market surveillance study plan that addresses the

deficiencies identified in the FDA letters dated September 29, 2014 and February 13, 2015. In addition, please notify this office in writing of the specific steps you have taken to correct the noted violations, as well as those actions performed to prevent recurrence for this order and future studies. Include documentation of the corrective actions you have taken. If your planned corrections will occur over time, please include a timetable for implementation of those corrections. If corrective actions cannot be completed within 15 calendar days, state the reason for the delay and the time within which the corrections will be completed.

Your study plan and response to this letter should be sent to:

522 Post-market Surveillance Studies Program
Food and Drug Administration
Center for Devices and Radiological Health
10903 New Hampshire Avenue
Building 66, Room 4278
Silver Spring, Maryland 20993-0002.

If you have any questions about the content of this letter please contact:

Attention: Albert E. Moyal, Engr.
Food and Drug Administration
Center for Devices and Radiological Health
Office of Compliance
Division of Bioresearch Monitoring
10903 New Hampshire Avenue
Building 66, Room 3451
Silver Spring, Maryland 20993-0002.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of a device. This letter pertains only to the issue of postmarket surveillance requirements for the ReWalk device subject to the 522 Order and does not necessarily address other obligations your firm has under the law.

Sincerely yours,
/S/
Jan B. Welch, MHS, MT (ASCP) SBB
Acting Director
Office of Compliance
Center for Devices and
Radiological Health

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