86 Harriet Ave Corporation DBA General Devices 6/1/16

Department of Health and Human Services

Public Health Service
Food and Drug Administration
New Jersey District Office
Waterview Corporate Center
10 Waterview Blvd. 3rd Floor
Parsippany, New Jersey 07054
Telephone: (973) 331-4900
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WARNING LETTER

June 01, 2016

16-NWJ-07

VIA UNITED PARCEL SERVICE
Mr. Curt M. Bashford
President & CEO
86 Harriet Ave. Corporation DBA General Devices
1000 River Street
Ridgefield, New Jersey 07657-1610

Dear Mr. Bashford:

During an inspection of your firm, located in Ridgefield, New Jersey, on June 2, 2015 through June 11, 2015, an investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures Carepoint EMS WorkStation/GEMS Series 4000, EIM lOS Prep-Check, EIM-107-20A Prep-Check Plus, Rosetta-Lt, and Rosetta-Rx. Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(h), these products are devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body.

This inspection revealed that these devices are adulterated within the meaning of section 501(h) of the Act, 21 U.S.C. *§* 351(h), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the current good manufacturing practice requirements of the Quality System regulation found at Title 21, Code of Federal Regulations (CFR), Part 820.

We received written responses from Mr. James Nejmeh, Director of Operations, dated June 29, 2015, and from Mr. Curt M. Bashford, President and CEO, dated September 11, 2015, respectively, concerning our investigator's observations noted on the Form FDA 483, List of Inspectional Observations, which was issued to Mr. Bashford on June 11, 2015. We address these responses below, in relation to each of the noted violations. These violations include, but are not limited to, the following:

1. Failure to adequately establish procedures for corrective and preventive action, as required by 21 CFR 820.100(a). For example:

A. Unsigned SOP titled "General Devices CAPA Policy," effective 2/27/13, does not require that various sources of quality data be analyzed to identify existing and potential causes of nonconforming products or recurring quality problems. The SOP does not require a CAPA root cause investigation for: 1) "known issues previously reviewed under CAPA"; 2) failed "purchased industry standard off shelf components"; 3) "normal wear & tear or age related" nonconforming products; and 4) nonconforming products caused by ''user abuse or damage."

B. The firm's service records dated between 3/4/13 and 6/2/15 indicates that at least **(b)(4)** 17-inch and 19-inch Carepoint EMS Workstation monitors or touchscreen monitors malfunctioned and were sent to the suppliers for an exchange. A supplier CAPA investigation for a root-cause determination has not been initiated. Examples

of service records in which the root cause was not determined include, but are not limited to:

- #1532, dated 05/15/2015: The screen had no display.
- #1619, dated 05/15/2015: The screen was on for a couple of seconds and went black.
- #1608, dated 05/26/2015: The monitor did not turn on during installation.

We reviewed your firm's written responses; however, the adequacy of your firm's responses cannot be determined at this time. We acknowledge that your firm's initial response, dated June 29, 2015, stated that your flrm will conduct an in-house audit of the firm'squality system and initiate corrective actions which were expected to be completed within 90 days "from receipt of official report" In your subsequent response, dated September 11, 2015, your firm outlined its implementation of corrective actions to address each of the noted observations in the Form FDA 483. However, the response did not provide any supporting documentation to demonstrate how your firm corrected each deficiency.

2. Failure to adequately establish design change procedures, as required by 21 CFR 820.30(i). For example:

A. Unsigned SOP titled "Change Notification System," dated 8/16/94, does not require that design changes be verified or validated prior to implementation.

B. There is a lack of a documented software validation for releasing the following Carepoint.exe versions for resolving issues from one customer site, which include, but are not limited to:

- #10089, dated 5/21/14: The unit kept alarming for an incoming ECG, but the ECG did not appear on the screen.
- #9169, dated 12/11/13: The unit continued to alarm audibly after a 12 Lead ECG came in.
- #8429, dated 05/21/13: The unit kept having audible alarms for an incoming 12 Lead ECG, but the 12 Lead ECG did not show up on the screen after the user selected View 12-Lead ECG.

C. Issue Ticket# 9808, dated 4/2/14, indicated that the audio between an iPad and Carepoint EMS WorkStation, Serial No. 0464, was not working. The unit's **(b)(4)** program was upgraded to version 1.01.26 to resolve the issue. There is a lack of documented software validation for the **(b)(4)** release.

We reviewed your firm's written responses; however, the adequacy of your firm's responses cannot be determined at this time. We acknowledge that your firm's initial response, dated June 29, 2015, stated that your firm will conduct an in-house audit of

the firm'squality system and initiate corrective actions which were expected to be completed within 90 days "from receipt of official report." In your subsequent response, dated September 11, 2015, your firm outlined its implementation of corrective actions to address each of the noted observationsin the Form FDA 483. However, the response did not provide any supporting documentation to demonstrate how your firm corrected each deficiency.

Our inspection also revealed that your firm failed to meet the requirements under 21 CFR 803.17 for developing, maintaining, and implementing written medical device reporting (MDR) procedures. Significant violations include, but are not limited to,the following:

3. Failure to establish an internal system which provides for the timely and effective identification, communication, and evaluation of events that may be subject to MDR requirements, as required by 21 CFR 803.17(a)(1). For example:

A. The SOP entitled "General Devices Medical Device Reporting (MDR) Policy", dated 2/25/98 and 2/27/14, does not require an establishmentof an internal system for timely and effective identification, communication, and evaluation of events thatmay be subject to MDR requirements.

B. There is a lack of a documented evaluation for the following complaints and/or service records for MDR reportability:

- Issue Ticket# 11821, dated 5/5/15, and Service Record# 1618, dated 6/2/15, indicated that Carepoint EMS WorkStation's, Serial No. 0180, radio froze-up and would not allow a caller to hang up due to a corrupted hard drive.
- Issue Ticket# 11503, dated 3/5/15, and Service Record# 1587, dated 3/5/15, indicated that Carepoint EMS WorkStation, Serial No. 0465, was not starting up due to a failed printed circuit board (DSP board).
- Issue Ticket# 10089, dated 5/21/14, indicated that Carepoint EMS WorkStation, Serial No. 0381, kept alarming that an ECG was received but the ECG did not appear on the screen.

We reviewed your firm's responses; however, the adequacy of your firm' s responses cannot be determined at this time. We acknowledge that your firm's initial response, dated June 29, 2015, stated that your firm will conduct an in-house audit of the firm's quality system and initiate corrective actions which were expected to be completed within 90 days "from receipt of official report." In your subsequent response, dated September 11, 2015, your firm outlined its implementation of corrective actions to address each of the noted observations in the Form FDA 483. However, the response did not provide any supporting documentation to demonstrate how your firm corrected each deficiency.

Your firm should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and civil money penalties.

Please notify this office in writing within fifteen business days from the date you receive this letter of the specific steps your firm has taken to correct the noted violations, as well as an explanation of how your firm plans to prevent these violations, or similar violations, from occurring again. Include documentation of the corrections and/or corrective actions (which must address systemic problems) that your firm has taken. If your firm's planned corrections and/or corrective actions will occur over time, please include a timetable for implementation of those activities. If corrections and/or corrective actions cannot be completed within fifteen business days, state the reason for the delay and the time within which these activities will be completed. Your firm's response should be comprehensive and address all violations included in this Waming Letter.

Your firm's response to this letter should be sent to: U.S. Food and Drug Administration, 10 Waterview Blvd., 3rd Floor, Parsippany, New Jersey 07054 (re: CMS #475178). If you have any questions about the contents of this letter, please contact Charles J.Chacko, Compliance Officer, at 1-973-331-4946 (phone) or 1-973-331-4969 (fax).

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your firm's facility. It is your firm's responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Inspectional Observations, FDA 483, issued at the close of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality management systems. Your firm should investigate and determine the causes of the violations, and take prompt action to correct the violations and bring the products into compliance.

Sincerely yours,
/S/
Craig W. Swanson
Acting District Director
New Jersey District

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