**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
FOOD AND DRUG ADMINISTRATION

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 6th & Kipling St. (P.O. Box 25087)<br>Denver, CO 80225-0087<br>(303)236-3000 Fax:(303)236-3100 | 4/13/2022-4/19/2022*<br>FEI NUMBER<br>3008313821 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Scott H. Siegel, President and CEO

| FIRM NAME | STREET ADDRESS |
|---|---|
| Cleartooth Electronics, Inc. | 106 Mineola Ct |
| CITY, STATE, ZIP CODE, COUNTRY<br>Boulder, CO 80303-4417 | TYPE ESTABLISHMENT INSPECTED<br>Medical Device Manufacturer |

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

*The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.*

**DURING AN INSPECTION OF YOUR FIRM I OBSERVED:**

## OBSERVATION 1

Procedures for design change have not been adequately established.

Specifically, you have not adequately established your Design Change Procedure, No. 9.0, Rev. 3.0, Effective date: 5/24/19 requiring evaluation/approval of proposed software changes prior to implementation. For example:

a) Software Change Request # 6121 (CR # 6121) was not approved/"activated" prior to implementing the software change as required. Evaluation of Change Request #6121 to assess impact/risks of the software change was first performed on 9/3/2019 as documented on Design Change Evaluation Form (QS-DX-9.1). This software change to "Improve handling of (b) (4) unable to create native thread exception" to address "master issue" - CI A19002 (Complaint investigation A19002, date received 2/21/2019), was implemented in software version (b) (4) on 9/25/2019; however, the change was not approved/"activated" by the product owner until 4/11/2022.

b) Software Change Request # 6305 (CR # 6305) was not approved/"activated" prior to implementing the software change as required. Evaluation of Change Request #6305 to assess impact/risks of the software change was first performed on 12/1/2020 as documented on Design Change Evaluation Form (QS-DX-9.1). This software change described as (b) (4) leaves unused threads after workers disconnect; too

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many threads made", was implemented in software version (b) (4) and (b) (4) on 12/31/2020 and 12/3/2020 respectively; however, the change was not approved/"activated" by the product owner until 1/22/2021.

Additionally, all evaluation/assessment terms used in the QS-DX-9.1 Design Change Evaluation Form, Revision 1.0 and the "Design Change Log 3 2016.xlsx" electronic record provided as the "Change Request Log" are not defined (i.e. Minor, Modest, Trivial, Prominent, Important).

## OBSERVATION 2

Procedures for receiving, reviewing, and evaluating complaints by a formally designated unit have not been adequately established.

Specifically, your Complaint Review Procedure, No. 21, Rev. 1.0, Effective Date: 12/27/18 and Technical Support Procedure, No. 21, Rev. 2.0, Effective Date: 8/5/19 (and previous revision, Rev. 1.0, effective date: 12/4/18) have not been adequately established as not all complaints are adequately processed/documented as required. For example:

Seven of the thirteen complaint records for complaints requiring investigation (i.e. B15003, F16001, B17008, F18001, B21001) did not include the name, address, and phone number of the complainants and any unique device identifier (UDI) or universal product code (UPC), and any other device identification(s) and control

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number(s) used. Moreover, thirteen of the thirteen records do not reflect date and signatures by the individual closing the complaint.

Nine of the thirteen Support Call Reports reviewed alleged product complaints but were not identified/documented as complaints and handled accordingly (i.e. 5/15/17, 14:35; 5/18/17, 15:33; 8/21/17, 12:10; 9/26/17, 10:15; 11/25/19, 14:45; 3/2/21, 14:15). Moreover, thirteen of the thirteen records do not reflect date and signatures by the individual closing the reports.

Further, the procedures neither delineate how these hybrid ( (b) (4) and (b) (4) records) records interface with one another nor how they are generated, identified, maintained, reviewed/authorized, controlled, and authenticated to include the required frequency, purpose and requirements for documenting review.

## OBSERVATION 3

Software validation activities and results for computers or automated data processing systems used as part of the quality system have not been documented.

Specifically, your firm utilizes software such as (b) (4) spreadsheet for creating, logging, storing, reviewing/editing, and managing quality system records such as support call logs, complaint logs, software/design change logs, verification and validation and software build logs; yet you have not validated the software for its intended use to date.

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## OBSERVATION 4

Document control procedures have not been established and maintained.

Specifically, your firm has not adequately established your Document Control Procedure, No. 13.0, Rev. 2.0, Effective Date: 12/20/18, as the procedure does not define how your digital quality system records are generated, identified, maintained, reviewed/authorized, controlled, and stored.

For example, there is no documentation of review and approval for use of complaint, service, software build and software change request logs that are (b) (4) spreadsheet digital records created, revised and maintained digitally.

Further, it does not define the process of periodically verifying "for accuracy" and authenticating digital records to include the purpose and requirements for documenting review of digital records and required frequency in hard copy records (i.e. Support Call Review Log, reviewed 3/31/22, Complaint Review Log, 10/29/21).

## OBSERVATION 5

Procedures for design transfer have not been adequately established.

Specifically, your Design Transfer Procedure, No. 12.0, Rev. 1.0, Effective Date: 12/13/18, has not been adequately established as it does not define "limited" " and "single" release of software builds and their respective review and approval requirements (i.e. Build # (b) (4) released as "Single" on 4/1/2022, Build (b) (4), released as "Limited" on 3/15/2022).

## *DATES OF INSPECTION

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4/13/2022(Wed), 4/14/2022(Thu), 4/15/2022(Fri), 4/18/2022(Mon), 4/19/2022(Tue)

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Investigator
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## Annotations to Observations

Observation 1: Not annotated

Observation 2: Not annotated

Observation 3: Not annotated

Observation 4: Not annotated

Observation 5: Not annotated

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."