DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214)253-5200 Fax:(214)253-5314	8/22/2019-9/5/2019* FEI NUMBER 3014268427

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Daniel C. Herbert, Founder	
FIRM NAME	**STREET ADDRESS**
Curewave Lasers LLC	4101 Mcewen Rd Ste 670
CITY, STATE, ZIP CODE, COUNTRY	**TYPE ESTABLISHMENT INSPECTED**
Dallas, TX 75244-5112	Medical Device Manufactuer

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 WE OBSERVED:

OBSERVATION 1

The design history file was not established.

Specifically,

As per your firm's procedure Design & Development, DES/0100, Issue: 1, Rev: 0. Your firm began design, manufacturing and distribution of the device Curewave Medicore, in 2017. During my review of your design control operations, I observed the following deficiencies:

a) Design Reviews: As per section 6.0-6.1.5, design reviews are to be conducted to evaluate the status of a design project, review the results of input, output, verification and validation activities, and review design changes, and documented on for DES/0100-4: Design Review Summary. Your firm did not document any design reviews for the device Curewave Medicore.

b) Design Input: As per section 4.0-4.1.3, design inputs consist of identification and documentation of the requirements of the device under design. Form DES/0100-3: Design Input Checklist is to

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be used as an aid in assuring that no aspect of design input is overlooked. Form DES0100-4: Design Input Details is to be used to document design input specifications. Your firm did not identify/ document design inputs for the Curewave Medicore.

c) Design Output: As per section 5.0-5.1.5, a total finished design out put consist of: it's packaging, labeling, associated specifications/drawings, and production and quality assurance specifications and procedures. Design outputs are to be documented on form DES/0100-4: Design Input Details and used to document that specifications have been met. The form DES/0100-5: The Design Output Summary, will be used to identify the characteristics if the design that are crucial to safe and proper functioning of the product and to identify output documents. The procedure goes on to state that the project manager will review and approve the design out documentation through each design phase and at regular scheduled design review meetings will assure the update of the DHF file. Your firm did not identify/ document design inputs for the Curewave Medicore.

d) Design Verification: As per section 7.0 - 7.1.6, verification activities and task are completed throughout the design process. These activities are review, analysis, test, inspections, etc. that are listed in the DES/0100-4: Design Input Details. Your procedure goes on to state the design verification can be performed on subassemblies and the entire completed product. Verification records will include a description of the methods (material, test, equipments, etc.) used, the results, the name(s) of the individual(s) completing the the verification, and the date, recorded on form DES/0100-8: Design Verification Summary. Your firm performed various design various activities including: (b) (4) using the Curewave Laser, (b) (4) (b) (4) These design verification activities were not performed nor documented as per the design verification section 7.1.6.

e) Design Validation: As per section 8.0- 8.1.5 , design validation is completed on initial production lots that have been produced under the same specification, production, and quality system methods, procedures, and equipment that will be used for routine production. Design validation must include (b) (4)

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(b) (4) The device Curewave Medicore has a Class-IV laser that is run and controlled by a software. Your firm did not adequately validate the (b) (4) interface software.

f) Risk Analysis: As per section 13 Guidance Document/Risk Management is outlined in Form TF/0100-Risk Management and Essential Requirements Check List. This describes the international standard on risk management in accordance with ISO14971 and also covers the identification of a risk management method used in product life cycle to assess design verification and/or validation activities as required, including methods or test used and acceptance criteria applied. Your firm did not perform risk analysis adequately as per the requirements of your procedure Guidance Document/Risk Management section 13.

OBSERVATION 2

Potential suppliers, contractors and consultants were not evaluated based on their ability to meet specified requirements.

Specifically, as per your firm's procedure titled, General Purchasing, PUR/0100, Issue: 1, Rev: 0, section 2.4, suppliers/vendors are to be evaluated (b) (4) Your firm has not completed any evaluation/qualification/assessment of any of the suppliers, vendors, or consultants. For example, your firm has not evaluated the top (b) (4) most critical suppliers for (b) (4) .

Your firm's procedure titled, Vendor Assessment Procedure, PUR/0200, Issue: 1, Rev: 0, states that each vendor will be assessed in (b) (4) areas on (b) (4) basis and a assessment for will be completed. However, your firm has not completed vendor assessments on your suppliers, contractors, and consultants.

Additionally, where as possible your firm does not have an agreement with any of the suppliers that they agree to notify the you the (manufacturer) of changes to the product or service so the manufactures may determine whether the changes may affect the quality of a finished device.

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OBSERVATION 3

Acceptance activities were not documented and maintained as part of the device history record.

Specifically, your firm has not established a procedure or maintained records for acceptance activities. Additionally, your firm did not maintain records that identify the inspections, test, or verification activities during the receiving, in-process, and finished device acceptance. These records shall include:

g) The acceptance activities performed
h) The dates acceptance activities were performed
i) The results
j) The signature of the individuals conducting acceptance activities
k) Equipment used to during acceptance activities

OBSERVATION 4

Quality audits were not performed at defined intervals to determine whether the quality system activities and results comply with quality system procedures.

Specifically, I requested and reviewed your firms procedure titled, Internal Quality Audits, Issue: 1, Rev: 0 and the procedure did not list defined intervals as to when quality audits shall be conducted. The firm began distribution of medical devices in 2017. Your firm has one documented quality audit dated July 2019.

OBSERVATION 5

A device master record has not been adequately maintained.

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Specifically, your firm has not implemented a device master record procedure. The following information was also not provided for the Curewave Medicore device:

Device Master Record

l) Production process specifications including the appropriate equipment specifications, production methods
m) Quality Assurance procedures and specifications including acceptance criteria
n) Packaging and labeling specifications, including methods and processes used
o) Installation, maintenance and servicing procedures and methods

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OBSERVATION 6

A device history record has not been maintained.

Specifically, your firm has not implemented a device history procedure. The following information was also not provided for the Curewave Medicore device:

Device History Record

p) Dates of manufacture
q) Quantity manufactured
r) The acceptance records
s) Primary identification label

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Review of the firm's DHF does not contain records to demonstrate that the design was developed in accordance with design plan and requirements as indicated in your Design & Development Procedure section 11.1.

OBSERVATION 7

Document control procedures have not been established.

Specifically, I requested and reviewed your firm's procedure, Change Control Procedure,QAP/0101 Issue: 1, Rev:0. The procedure indicates that the firm's documents must include the following information: approval signature and dates, documentation affected, effective date of change, etc.

Additionally, the firm's document Change Control Procedure,QAP/0101 Issue: 1, Rev:0 itself was not signed, dated and was not adequately implemented. When I reviewed the firm's quality procedures I observed that none of the procedures had dates, signatures, or approval/implementation dates. Your firm's Founder stated that these procedures have been in place since 2017.

OBSERVATION 8

Certification was not based upon a test, in accordance with the standard.

Specifically, your firm manufacturers and distributes the device Curewave Medicore, which is equipped with a Class-IV laser, specified at 44 watts and 1280 nm wavelength. Your firm has not based the certification of this

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Class-IV laser upon a test, in accordance with the standard, or testing program which is in accordance with good manufacturing practices.

OBSERVATION 9

You did not submit an annual report by the September 1 deadline for products requiring one.

Specifically, since 2017 your firm has not submitted any annual reports to the Food and Drug Administration for your Curewave Medicore laser device. Your firm has manufactured and distributed (b) (4) devices that are equipped with a Class-IV laser. Additionally, your firm did not submit a product (initial report) to the FDA, prior to distributing the Class-IV laser device.

OBSERVATION 10

The medical laser product does not incorporate in each Class III or IV medical laser product a means for the measurement of the level of that laser radiation intended for irradiation of the human body, having an error in measurement of no more than (b) (4) when calibrated in accordance with the CFR requirements.

Specifically,

Your firm manufactures and distributed a Class-IV laser that consist of 44 watts and 1280 nm wavelength . Your firm does not incorporate in the laser device, means for measuring the level of radiation (within a (b) (4) error), when calibrated.

Additionally, your firm does not have a calibration procedure or schedule for the following measuring devices used during manufacturing and final release of the device:

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(b) (4)

OBSERVATION 11

A label bearing the wording: "Laser aperture". is not affixed to the medical laser product, in close proximity to the aperture through which was emitted accessible laser radiation in excess of the accessible emission limits of Class I.

Specifically, your firm manufactures and distributes the device Curewave Medicore, which is equipped with a Class-IV laser, specified at 44 watts and 1280 nm wavelength. Since 2017, your firm manufactured and distributed (b) (4) devices. The devices distributed do not have the "Laser aperuture" label affixed.

OBSERVATION 12

An identification label failed to provide the name and address of the individual or company under whose name the product was sold.

Specifically, your firm manufactures and distributes Curewave Medicore, which is equipped with a Class- IV laser, specified at 44 watts and 1280 nm wavelength. Since 2017, your firm manufactured and distributed (b) (4) medical devices. The following information was missing from the labels:

t) Complete address of firm
u) Month and year the device was manufactured

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***DATES OF INSPECTION**
8/22/2019(Thu), 8/27/2019(Tue), 8/28/2019(Wed), 9/05/2019(Thu)

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Annotations to Observations

Observation 1: Promised to correct

Observation 2: Promised to correct

Observation 3: Promised to correct

Observation 4: Promised to correct

Observation 5: Promised to correct

Observation 6: Promised to correct

Observation 7: Promised to correct

Observation 8: Promised to correct

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Annotations to Observations

Observation 9: Promised to correct

Observation 10: Promised to correct

Observation 11: Promised to correct

Observation 12: Promised to correct

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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."