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	02/11/20-02/20/20*
	FEI NUMBER 3014498660

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mark H. White, President & CEO

FIRM NAME	STREET ADDRESS
NEXALIN TECHNOLOGY INC.	1776 Yorktown St Ste 550
CITY, STATE, ZIP CODE, COUNTRY Houston, TX 77056-4180	TYPE ESTABLISHMENT INSPECTED Specification Developer

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

A device master record has not been maintained.

Specifically,

Your firm, Nexalin Technology Inc, did not have a Device Master Record for your Class 3 device, a transcranial electrotherapy stimulator, TESA (510K # K024377, cleared 07/21/2003), intended for use in reducing the symptoms of depression (Class 3, requiring a PMA), anxiety (Class 2) and insomnia (Class 2); has not been created to include, or refer to the location of, the following:

(a) Device specifications including appropriate drawings, composition, formulation, component specifications, and software specifications;
(b) Production process specifications including the appropriate equipment specifications, production methods, production procedures, and production environment specifications;
(c) Quality assurance procedures and specifications including acceptance criteria and the quality assurance equipment to be used;
(d) Packaging and labeling specifications, including methods and processes used; and
(e) Installation, maintenance, and servicing procedures and methods.

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	Jocelyn C Turner, Investigator	X Jocelyn C Turner Investigator Signed By: Jocelyn C. Turner -S Date Signed: 02-20-2020 11:28:45	02/20/20

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Your most recent Internal Audit, conducted by an external Auditor, (b) (4), in December 2017, listed as issue # 17480: Incomplete Design Master Record; which was described as a Category 1 risk level; Device Recall – Quality problem may result in device recall or cause injury to patient or operator.

- A corrective action for this CAPA issue was not addressed.
- A Device Master record was not defined and documented.

NEXALIN Inc, began in 2010. There were (b) (4) TESA, Class 3 medical devices in distribution.

At the time of this inspection, 2020, your firm could account for (b) (4) units, in which (b) (4) are currently being leased by medical practices, to treat patients for anxiety, depression and insomnia; in (b) (4)
(b) (4)

OBSERVATION 2
Procedures for design control have not been established.

Specifically, your firm has not implemented a Design Control procedure.

On 02/11/2020, your Quality System consultant firm submitted a Design Control procedure (Document No. NEX-QSD-00002, Revision B, set for approval on 02/11/2020). Revision A was effective 01/07/2020.

This procedure outlines your firm's Design Control process as 4 phases:

1. **Design Control Phase I (Requirements and planning)**

   The Phase I activities Phase I include ensuring all of design input information and plans are provided, reviewed and approved.

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2. **Design Control Phase II (Design, Development & Test)**

   During Phase II, design, development and testing occurs based on the input documents created in Phase I.

3. **Design Control Phase III (Verification)**

   During Phase III, the primary activities are the verification of the design output to demonstrate they meet all of the design inputs. In particular, integration testing and verification testing will take place. *(However, Design Control* (b) (4) *states that the hardware & software is not under any design control.)*

4. **Design Control Phase IV (Design Transfer)**

   The activities are focused on ensuring that the design that was verified is adequately translated into production specifications and procedures.

This procedure is inadequate because,

(a) There is no design and development plan that documents responsibility, interfaces with groups, such as your contract manufacturer and other quality consultants, the activities that need to be conducted, evaluated and reviewed as documented for Phase I.

(b) These design control process steps are inadequate as they do not include the creation of design outputs - “specifications, acceptance criteria”, prior to the Verification step (Phase III).

(c) There is no designated Design Validation and your Class 3, Transcranial Electrotherapy Stimulator-A (TESA) device

(d) This is a Class 3 medical device with imbedded software that controls the device and there is no

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validation step prior to Design Transfer. Software controlled medical devices must be validated.

(e) The Design Review process is not included in the 4 phases of Design Control.

(f) Design changes (Section 7.2.8) does not include the requirement to identify, document, validate or where appropriate, verify, review and approve design changes prior to their implementation.

For example,

Your firm is in the process of (b) (4)
(b) (4)
(b) (4)

Your Design management team stated that (b) (4) but there were no Design Change procedures in place prior to their implementation.

Your most recent Internal Audit, conducted by an external Auditor, (b) (4) in December 2017, listed 08 issues in which 03 were design control related:

(a) Issue # 17479: Incomplete Design History File, described as a Category 1 risk level; a CAPA that if not completed, may results in, or cause injury to, the patient or operator.

(b) Issue # 17480: Incomplete Device Master Record; described as a Category 1 risk level; a CAPA that if not completed, may results in, or cause injury to, the patient or operator.

(c) Issue # 17481: Missing Device History Records; described as a Category 2 risk level; a CAPA that warrants Competent Authority Official Action – this Quality problem may result in an OAI or warning letter from the FDA or other official action from a Competent Authority.

A Design History File, Device Master record and Device History Records were not defined and documented as a corrective action to this CAPA.

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OBSERVATION 3

Corrective and preventive action activities and/or results have not been documented.

Specifically, your firm, NEXALIN Technology, is a Specification Developer for the Class 3 medical device, Transcranial Electrotherapy Stimulator-A (TESA), 510K # K024377 (cleared 07/21/2003).

In December 2017, your firm hired an external Internal Auditor, (b) (4) to evaluate your current Quality System.

This Auditor, upon completing the internal audit, submitted to you a list of CAPA(s) in the form of an EXCEL-like spreadsheet,

The 08 issues documented and submitted to FDA during your inspection included:

Issue ID	CAPA description	# days open	Risk Category
17477	Lapse of Quality System	218	Category 1
17479	Incomplete Design History File	526	Category 1
17480	Incomplete Design Master Record	526	Category 1
17481	Missing Device History Records - no DHRs	218	Category 2
17482	Missing Complaints Records - not maintained	525	Category 2
17483	Missing Distribution Records - not maintained	206	Category 2
17484	Lapsed registration and listing with US FDA	038	Category 2
29779	Front Harness Wire Issue	227	Category 2

❖ *"Category 1", is a CAPA that if not completed, may results in, or cause injury to, the patient or operator.*

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❖ *"Category 2" is a CAPA that warrants Competent Authority Official Action – this Quality problem may result in an OAI or warning letter from the FDA or other official action from a Competent Authority.*

I requested the supporting documents for these issues found by your external Auditor and your President stated that in November 2019, a new Quality System consultant was hired. The decision was made to not make any of the other corrections suggested by your Quality System consultant, (b) (4).

Per NEXALIN CAPA Procedure (NEX-QSD-00088, Rev A, 02/11/2020), the form NEX-FRM-00003 will be used and a description shall be documented.

During root cause analysis, the Operations Lead shall assign the CAPA to an owner. The owner shall perform an evaluation and document the root cause analysis.

An action plan will be documented.

There will be an effectiveness check conducted for verification that the corrective action implemented did not adversely affect the ability to meet applicable regulatory requirements or safety and performance of the medical device.

Finally, the CAPA will be closed.

The response time will be as follows:

Root Cause Analysis	Action Plan	Action Implementation	Verification of Effectiveness	CAPA Closure
(b) (4) days	(b) (4) days	(b) (4) days/based on each individual situation	(b) (4) days/Dependent on action implanted.	Within (b) (4) of verification of effectiveness

Corrective and Preventive actions were not conducted per this CAPA procedure.

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OBSERVATION 4

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

Specifically, your firm's Complaint procedure, NEXALIN Corrective / Preventive Action and Customer Complaint (NEX-QSD-00088, Rev A, 02/11/2020), does not address complaint evaluation.

It fails to address the following:

(a) Complaints will be processed within a uniform and timely manner;
(b) Oral, written and electronic complaints will be documented upon receipt;
(c) Complaints will be evaluated to determine if they represent an event which is required to be reported to FDA, MDR Reporting (803) and MDR reportable complaints shall be maintained in a separate file.
(d) All complaints will be reviewed & evaluated to determine if an investigation is necessary. If not, a justification will be documented to include the name of the individual person responsible for the decision not to investigate.
(e) All complaints that represent a possible failure of the device, labeling or packaging to meet any of its specifications shall be reviewed, evaluated and investigated.
(f) Investigational records shall include a determination of whether the device failed to meet specifications; was being used for treatment or diagnosis and the relationship, if any, of the device to the reported incident or adverse event.

Your most recent Internal Audit, conducted by an external Auditor, (b) (4), in December 2017, listed as issue # 17482: *MISSING Complaint records*; which was described as a Category 2 risk level; a CAPA that warrants Competent Authority Official Action – this Quality problem may result in an OAI or warning letter from the FDA or other official action from a Competent Authority.

A corrective action for this CAPA issue was not addressed.

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A Complaint procedure was not defined, documented or implemented.

***DATES OF INSPECTION**

2/11/2020(Tue), 2/12/2020(Wed), 2/13/2020(Thu), 2/18/2020(Tue), 2/19/2020(Wed), 2/20/2020(Thu)

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Annotations to Observations

Observation 1:

Observation 2:

Observation 3:

Observation 4:

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