DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1431 Harbor Bay Parkway Alameda, CA 94502-7070 (510)337-6700 Fax:(510)337-6702	6/22/2017-7/5/2017*
	FEI NUMBER 2919128

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Dustin M. Dequine , Operations Manager

FIRM NAME	STREET ADDRESS
Hand Biomechanics Lab Inc	77 Scripps Dr Ste 104
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Sacramento, CA 95825-6209	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

An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device may have caused or contributed to a death or serious injury.

Specifically,
During the time period between 6/19/2015 and 3/30/2017, your firm received four complaints related to medical events that patients developed pin site infections while being treated your firm's orthopedic external fixation devices (Digit Widget devices). In one of the events, the physician removed the device as a result of the infection. In other events, the physicians prescribed antibiotics to treat infections. Your firm did not report these medical events to FDA.

OBSERVATION 2

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

Specifically,
Your complaint handling procedure titled "Negative Customer Feedback and Complaint Handling", SOP001, states a requirement for documenting patient outcome. Your firm received a complaint on 9/15/2015 that was related to pin site infection. The complaint report stated that a patient developed "a track infection from the side to side movement of the transverse pin through the bone" while being

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Quynh Strandberg, Investigator 7/5/2017 X Quynh Strandberg Quynh Strandberg Investigator Signed by: Quynh H. Strandberg -S	7/5/2017

treated with your firm's TurnKey FCS device. Your firm did not make attempt(s) to obtain additional information regarding patient outcome in order to determine whether the event represented a MDR reportable event.

OBSERVATION 3
A process whose results cannot be fully verified by subsequent inspection and test has not been adequately validated according to established procedures.

Specifically,
Your firm's package seal processes (to provide a sterile barrier for finished devices) were not adequately validated. For example, your firm's package seal validation protocols for WristJack, TurnKey FCS, and Digit Widget did not include a requirement for testing samples taken from actual production lots for performance qualification. According to your Quality Manager, empty packages were sealed then tested.

OBSERVATION 4
A validated process was not revalidated when changes or process deviations occurred.

Specifically,
Your firm started using a (b) (4) ((b) (4)) in October 2016. The (b) (4) (b) (4) is used by your firm to form a sealed package that provides a sterile barrier for finished devices. Your firm did not adequately revalidate package seal processes. According to your Quality Manger, empty packages were sealed then tested. In addition, no leak test was performed.

OBSERVATION 5
Procedures for corrective and preventive action have not been adequately established.

Specifically,
Your CAPA procedure titled "Corrective and Preventive Action (CAPA)", SOP026, states requirements for determination, implementation, and documentation of corrective and preventive actions when a CAPA event has been identified. During the time period between 2/24/2015 and 2/3/2017, your firm

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1431 Harbor Bay Parkway Alameda, CA 94502-7070 (510)337-6700 Fax:(510)337-6702	6/22/2017-7/5/2017*
	FEI NUMBER 2919128

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Dustin M. Dequine , Operations Manager

FIRM NAME	STREET ADDRESS
Hand Biomechanics Lab Inc	77 Scripps Dr Ste 104
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Sacramento, CA 95825-6209	Manufacturer

identified ten CAPA events where your firm's finished device packages failed (b) (4) tests during routine production. However, your firm did not take action(s) to prevent recurrence of the quality issue.

OBSERVATION 6
Procedures for monitoring and control of process parameters for a validated process have not been established.

Specifically,
Your firm did not establish monitoring procedures to monitor the validated package seal process parameters of time, temperature and pressure. Sealing time, temperature and pressure were not monitored during routine production.

Annotations to Observations

Observation 1: Not annotated
Observation 2: Not annotated
Observation 3: Not annotated
Observation 4: Not annotated
Observation 5: Not annotated
Observation 6: Not annotated

***DATES OF INSPECTION**
6/22/2017(Thu),6/23/2017(Fri),6/26/2017(Mon),6/27/2017(Tue),6/30/2017(Fri),7/05/2017(Wed)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Quynh Strandberg, Investigator 7/5/2017 X Quynh Strandberg Quynh Strandberg Investigator Signed by: Quynh H. Strandberg -S	7/5/2017

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
22215 26th Ave SE Suite 210 Bothell, WA 98021 (425)302-0340 Fax:(425)302-0404	7/6/2017-7/7/2017
	FEI NUMBER 3005026995

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Michael B. Stevens , Vice President

FIRM NAME	STREET ADDRESS
Neuro-Fitness LLC	33631 #2 Redmond-Fall City Rd.
CITY, STATE, ZIP CODE, COUNTRY Fall City, WA 98024	TYPE ESTABLISHMENT INSPECTED 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 receiving, reviewing, and evaluating complaints by a formally designated unit have not been adequately established.

Specifically, your firm's Complaint Handling Procedure, QSP-6, requires the QSF-6-1 Complaint Form (Effective Date 8/31/2012) to be completed for all complaints. The approved version of the QSF-6-1 Complaint Form contains the following sections: Complaint Investigation Required; Response to Complainant; and Corrective Action Required. Your firm is currently using an unapproved version of the QSF-6-1 Complaint From which does not contain these sections.

OBSERVATION 2

Documents that were not approved were observed at a location where they are being used.

Specifically, your firm is currently using an unapproved version of the QSF-6-1 Complaint Form.

OBSERVATION 3

Procedures to ensure that all purchased or otherwise received product and services conform to specified requirements have not been adequately established.

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Stephen R Souza, Investigator 7/7/2017 X Stephen R Souza Stephen R Souza Investigator Signed by: Stephen R. Souza -S	7/7/2017

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
22215 26th Ave SE Suite 210 Bothell, WA 98021 (425)302-0340 Fax:(425)302-0404	7/6/2017-7/7/2017
	FEI NUMBER 3005026995

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Michael B. Stevens , Vice President	
FIRM NAME Neuro-Fitness LLC	STREET ADDRESS 33631 #2 Redmond-Fall City Rd.
CITY, STATE, ZIP CODE, COUNTRY Fall City, WA 98024	TYPE ESTABLISHMENT INSPECTED Manufacturer

Specifically, your firm's Purchasing Controls procedure, QSP-4, requires periodic re-evaluation of supplier acceptability. This procedure also requires your frim to maintain an Approved Vendor List. Your firm does not have documentation showing that suppliers are being re-evaluated. Your firm does not have an Approved Vendor List.

Annotations to Observations

Observation 1: Promised to correct
Observation 2: Promised to correct
Observation 3: Promised to correct

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Stephen R Souza, Investigator 7/7/2017 X Stephen R Souza Stephen R Souza Investigator Signed by: Stephen R. Souza -S	7/7/2017

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue Silver Spring, 20993 (301)594-4695 Fax:(301)594-4715	2/6/2017-2/8/2017 FEI NUMBER 3003793605

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Ms. Tomoko Hitomi , President

FIRM NAME	STREET ADDRESS
Ever Corporation	Sakitama 8-45
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Kuroiso City, Tochigi, 325-0033Japan	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

A process whose results cannot be fully verified by subsequent inspection and test has not been validated according to established procedures.

Specifically, your (b) (4) is used to (b) (4) and is intended to be (b) (4) . This (b) (4) and has never been validated to demonstrate that the (b) (4) is adequate for its intended use and meets the specifications of the intended (b) (4) .

In addition, your firm lacks procedures specific to the (b) (4) , other than (b) (4) .

OBSERVATION 2

Products that do not conform to specifications are not adequately controlled.

Specifically, On 02/06/2014, I noted that your Non-conformance Procedure (b) (4) , dated 04/01/2014, states that (b) (4) This procedure does not include conducting an investigation to determine the cause of the non-conformance and implementing corrective actions and preventive actions.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Kenneth Boehnen, Investigator	Revoked cert ficate X Kenneth Boehnen Kenneth Boehnen Investigator Signed by: Kenneth Boehnen -S	2/8/2017

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue Silver Spring, 20993 (301)594-4695 Fax:(301)594-4715	2/6/2017-2/8/2017 FEI NUMBER 3003793605

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Ms. Tomoko Hitomi , President

FIRM NAME	STREET ADDRESS
Ever Corporation	Sakitama 8-45
CITY, STATE, ZIP CODE, COUNTRY Kuroiso City, Tochigi, 325-0033Japan	TYPE ESTABLISHMENT INSPECTED Medical Device Manufacturer

You stated that your firm has never documented a non-conformance. However, the (b) (4) below listed DHRs indicate that product non-conformances occurred during various assembling steps. These non-conformances were not documented and investigated to determine the root cause, corrective actions or preventative actions. Additionally, these non-conformances are not tracked and trended or discussed in management review meetings.

DHR Number	Quantity Ordered	Quantity Prepared	Quantity Produced	% of Non-conformance
(b) (4)				

OBSERVATION 3
Procedures for device history records have not been established.

Specifically, you have not established written procedures for maintaining device history records.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Kenneth Boehnen, Investigator Revoked certificate X Kenneth Boehnen Kenneth Boehnen Investigator Signed by: Kenneth Boehnen -S	2/8/2017

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue Silver Spring, 20993 (301)594-4695 Fax:(301)594-4715	2/6/2017-2/8/2017
	FEI NUMBER 3003793605

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Ms. Tomoko Hitomi , President

FIRM NAME	STREET ADDRESS
Ever Corporation	Sakitama 8-45
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Kuroiso City, Tochigi, 325-0033Japan	Medical Device Manufacturer

OBSERVATION 4

Records of acceptable suppliers have not been established.

Specifically, you do not maintain supplier qualification records for vendors that supply components used to manufacture your Class II medical needle devices including but not limited to the following components supplied by (b) (4) suppliers: (b) (4) .

OBSERVATION 5

Written MDR procedures have not been developed.

Specifically, you have not established written Medical Device Reporting procedures.

Annotations to Observations

Observation 1:	Promised to correct
Observation 2:	Promised to correct by 04/10/2017
Observation 3:	Promised to correct by 04/10/2017
Observation 4:	Promised to correct
Observation 5:	Promised to correct by 04/10/2017

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Kenneth Boehnen, Investigator Revoked certificate X Kenneth Boehnen Kenneth Boehnen Investigator Signed by: Kenneth Boehnen -S	2/8/2017

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue Silver Spring, 20993 (301)594-4695 Fax:(301)594-4715	2/6/2017-2/9/2017
	FEI NUMBER 3000164103

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Ian Levine , President

FIRM NAME	STREET ADDRESS
AMD Medicom Inc. (GRANBY PLANT)	209 Rue York
CITY, STATE, ZIP CODE, COUNTRY Granby, Quebec, J2G2B9	TYPE ESTABLISHMENT INSPECTED 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 corrective and preventive action have not been established.

Specifically,

Corrective and preventive actions lack documentation of the implementation of the corrective and preventive actions identified as required to address the root cause of the identified problem. Examples include:

Non-conformance number (b) (4), dated 1/8/2016, which was (b) (4) received from (b) (4) with black spots. The corrective and preventive action was to (b) (4). There was no documentation that the (b) (4) was implemented. The action was signed and dated on 1/11/2016 as completed.

CAPA number (b) (4), which was opened due to customer complaints of material falling apart, linting and fuzzy. The corrective/preventive action was to (b) (4). There was no documentation that the (b) (4). The CAPA was closed and verified as effective.

CAPA-(b) (4), which was opened due to (b) (4) received with rolled edges. The (b) (4) gets blocked during the (b) (4) process. The immediate corrective action was to have the (b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Frank J Marciniak, Investigator - Dedicated Device Cadre	X	2/9/2017

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue Silver Spring, 20993 (301)594-4695 Fax:(301)594-4715	2/6/2017-2/9/2017
	FEI NUMBER 3000164103

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Ian Levine , President

FIRM NAME	STREET ADDRESS
AMD Medicom Inc. (GRANBY PLANT)	209 Rue York
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Granby, Quebec, J2G2B9	Manufacturer

(b) (4)
There was no documentation that the action was implemented. The CAPA was closed.

OBSERVATION 2
A device master record has not been maintained.

Specifically, the device master record for the ophthalmic sponges did not include the device specifications, production process specifications, quality assurance specifications, and packaging and labeling specifications.

OBSERVATION 3
Procedures to prevent contamination of equipment or product by substances that may have an adverse effect on product quality have not been adequately established.

Specifically, the (b) (4) . There was no requirement for employees to (b) (4) .

Annotations to Observations

Observation 1: Promised to correct within 3 Weeks
Observation 2: Promised to correct within 3 Weeks
Observation 3: Corrected and verified

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Frank J Marciniak, Investigator - Dedicated Device Cadre	X	2/9/2017

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue Silver Spring, 20993 (301)594-4695 Fax:(301)594-4715	2/13/2017-2/16/2017 FEI NUMBER 3002772505

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Antoni Jauma , Managing Director

FIRM NAME	STREET ADDRESS
Diagnostic Grifols, S.A.	Passeig Fluvial, 24
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Parets Del Valles, Barcelona, 08150Spain	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

An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Specifically, your firm did not submit an MDR report for all reportable events within thirty days of becoming aware of the event.

For example, Complaint # (b) (4) , dated 05/15/2015, involved "(b) (4) " This event was reported by your firm only on 12/02/2015, 201 days after your firm became aware of the incident.

OBSERVATION 2

Potential suppliers were not evaluated and selected based on their ability to meet specified requirements.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Roy Baby, Investigator 2/15/2017 X Roy Baby Roy Baby Investigator Signed by: Roy Baby -S	2/16/2017

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue Silver Spring, 20993 (301)594-4695 Fax:(301)594-4715	2/13/2017-2/16/2017 FEI NUMBER 3002772505

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Antoni Jauma , Managing Director

FIRM NAME	STREET ADDRESS
Diagnostic Grifols, S.A.	Passeig Fluvial, 24
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Parets Del Valles, Barcelona, 08150Spain	Medical Device Manufacturer

Specifically, your firm's Supplier Management procedure, (b) (4), dated 11/18/2016, requires (b) (4). However, your firm did not conduct or document the evaluations of your component suppliers, including the (b) (4) suppliers.

For example:

A. Your firm has been using an (b) (4), since 2011. Your firm did not document the evaluation and selection of this critical supplier. In addition, your firm did not follow your procedure in auditing the supplier.

B. Your firm has been using an (b) (4) supplier, (b) (4), since 2008. Your firm did not document the evaluation and selection of this component supplier.

C. Your firm has been using the (b) (4) supplier, (b) (4), since 2008. Your firm did not document the evaluation and selection of this component supplier.

OBSERVATION 3
Sampling plans are not based on valid statistical rationale.

Specifically, your firm did not provide any statistical rationale to justify the sampling method for incoming raw material inspection.

For example,

A. Your incoming inspection for (b) (4) requires only a (b) (4)

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue Silver Spring, 20993 (301)594-4695 Fax:(301)594-4715	2/13/2017-2/16/2017
	FEI NUMBER 3002772505

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Antoni Jauma , Managing Director

FIRM NAME	STREET ADDRESS
Diagnostic Grifols, S.A.	Passeig Fluvial, 24
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Parets Del Valles, Barcelona, 08150Spain	Medical Device Manufacturer

(b) (4) . The lot size for a recent shipment was (b) (4) .

B. Your incoming inspection for (b) (4) requires only (b) (4) .
The batch size for a recent shipment was (b) (4)

Annotations to Observations

Observation 1: Promised to correct
Observation 2: Promised to correct
Observation 3: Promised to correct

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Roy Baby, Investigator 2/15/2017 X Roy Baby Roy Baby Investigator Signed by: Roy Baby -S	2/16/2017