DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION				
DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION			
1431 Harbor Bay Parkway	6/22/2017-7/5/2017*			
Alameda, CA 94502-7070	FEI NUMBER			
(510)337-6700 Fax:(510)337-6702	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 Quynh Strandberg,	Investigator	7/5/2017 X Quynh Strandberg Quynh Strandberg Investigator Signed by Quynh H. Strandberg -S	DATE ISSUED
FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE	INSPECTIONAL OBSERVATIO	DNS	PAGE 1 OF 3 PAGES

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION					
DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION				
1431 Harbor Bay Parkway	6/22/2017-7/5/2017*				
Alameda, CA 94502-7070	FEI NUMBER				
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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				

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) 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

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FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE	INSPECTIONAL OBSERVATIO	DNS	PAGE 2 OF 3 PAGES

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION					
DATE(S) OF INSPECTION					
6/22/2017-7/5/2017*					
FEI NUMBER					
2919128					
STREET ADDRESS					
77 Scripps Dr Ste 104					
TYPE ESTABLISHMENT INSPECTED					
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	Amotations to Observations			
Observation 1: Observation 2:	Not annotated				
Observation 3:	Not annotated				
Observation 4:	Not annotated				
Observation 5:	Not annotated				
Observation 6:	Not annotated				
Observation 0.	Not annotated				
*DATES OF IN	NSPECTION				
		2017(Mon),6/27/2017(Tue),6/30/2017(Fri),7/05/2017	7(Wed)		
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SEE REVERSE	EMPLOYEE(S) SIGNATURE Quynh Strandberg,	Investigator 7/5/2017	DATE ISSUED		
OF THIS PAGE	guyim beranaberg,	X Quynh Strandberg	17572011		
		Quyth Strandberg Quyth Strandberg Investigator			
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FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE	INSPECTIONAL OBSERVATIONS	PAGE 3 OF 3 PAGES		

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	7/6/2017-7/7/2017				
Bothell, WA 98021	FEI NUMBER				
(425)302-0340 Fax: (425)302-0404	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 TYPE ESTABLISHMENT INSPECTED					
Fall City, WA 98024	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					
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FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE	INSPECTIONAL OBSERVATIO	ONS		PAGE 1 OF 2 PAGES

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CITY, STATE, ZIP CODE, COUNT Fall City, WA		TYPE ESTABLISHM Manufact			
rait City, WA	. 96024	Manufact			
supplier accepta Your firm does	ar firm's Purchasing Contro bility. This procedure also not have documentation sh proved Vendor List.	requires your frim	to maintain an Approve	ed Vendor Lis	
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			Investigator Signed by: Stephen R. Souza -S		
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	DEPARTMENT OF HEAD FOOD AND DRU	LTH AND HUMA		
DISTRICT ADDRESS AND PHON	NE NUMBER	O ADMINISTRATI	DATE(S) OF INSPECTION	
10903 New Han			2/6/2017-2/8/2017 FEI NUMBER	
Silver Spring (301)594-4695	g, 20993 5 Fax:(301)594-4715		3003793605	
NAME AND TITLE OF INDIVIDUA				
Ms. Tomoko Hi	itomi , President	STREET ADDRESS		
Ever Corporat	zion	Sakitama	8-45	
CITY, STATE, ZIP CODE, COUN	^{TRY} , Tochigi, 325-0033Japan	TYPE ESTABLISHME	TINSPECTED	
observations, and do observation, or have action with the FDA	observations made by the FDA representative(s not represent a final Agency determination reg implemented, or plan to implement, corrective representative(s) during the inspection or subn tact FDA at the phone number and address abo	arding your com action in respon nit this information	pliance. If you have an objection se to an observation, you may disc	regarding an cuss the objection or
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Silver Spr					FEI NUMBER		
(301)594-4695 Fax: (301)594-4715				30037936	05		
NAME AND TITLE OF IND	NVIDUAL TO WHOM REPOR	T ISSUED					
Ms. Tomoko	Hitomi , F	President					
FIRM NAME			2	STREET ADDRESS			
Ever Corpo				Sakitama			
(7.5.5.5 C) C) C (7.6.00) (7.6.00)	1000000	L, 325-0033J	apan			nufacturer	
listed DHRs non-conform or preventation	indicate that nances were n	product non-contract documented Additionally, the	conformance l and invest	es occurred igated to d	d during va etermine th	lowever, the (b) prious assemblin ne root cause, co acked and trend	g steps. These rrective actions
DHR	Quantity	Quantity	Quantity	% of N	lon-	1	
Number	Ordered	Prepared	Produced	NORON DALAPSAN	mance		
OBSERVA		1 1			1		
Procedures f	or device hist	ory records ha	ve not been	establishe	d.		
Specifically, you have not established written procedures for maintaining device history records.							
	EMPLOYEE(S) SIG		5 6 18	21	a :	153 Received our firsts	DATE ISSUED
SEE REVERS	See 200 and a second se	Boehnen, In	vestigato	r		Revoked cert ficate	2/8/2017
UT THIS FAC					8	Kenneth Boehnen Kenneth Boehnen Investigator Signed by: Kenneth Boehnen -5	
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FORM FDA 483 (09/08) PREVIC	OUS EDITION OBSOLETE	INSI	PECTIONAL C	DBSERVATION	NS	PAGE 2 OF 3 PAGES

	DEPARTMENT OF HEAL FOOD AND DRU(TH AND HUMAN GADMINISTRATION		
DISTRICT ADDRESS AND PHON	E NUMBER		ATE(S) OF INSPECTION	
	npshire Avenue		2/6/2017-2/8/2017 EI NUMBER	
Silver Spring	95 Fax: (301)594-4715		3003793605	
NAME AND TITLE OF INDIVIDUA	towi, President			
FIRM NAME	comi, president	STREET ADDRESS		
Ever Corporat		Sakitama 8		
CITY, STATE, ZIP CODE, COUNT	Tochigi, 325-0033Japan	TYPE ESTABLISHMENT	INSPECTED	
Specifically, you to manufacture components sup	ptable suppliers have not been estal u do not maintain supplier qualifica your Class II medical needle device plied by (b) (4) suppliers: (b) (4)	tion records f s including b	ut not limited to the follow	-
	Annotations	o Observati	ons	
Observation 1:	Promised to correct	U Observati	0115	
Observation 2:	Promised to correct by 04/10	/2017		
Observation 3:	Promised to correct by 04/10			
Observation 4:	Promised to correct	2017		
Observation 5:	Promised to correct by 04/10	/2017		
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SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Kenneth Boehnen, Investigato	or	Revolved cert frate Kenneth Boehnen Kenneth Boehnen Investigator	DATE ISSUED 2/8/2017
			Signed by: Kenneth Boehnen -S	2
FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE INS	PECTIONAL OB	SERVATIONS	PAGE 3 OF 3 PAGES

		OF HEALTH AND HUM AND DRUG ADMINISTRAT			
DISTRICT ADDRESS AND PHON	NE NUMBER		DATE(S) OF INSPECTION 2/6/2017-2/9/2017		
Silver Spring	mpshire Avenue g, 20993 5 Fax:(301)594-4715		2/6/2017-2/9/20 FEI NUMBER 3000164103	17	
NAME AND TITLE OF INDIVIDUA	L TO WHOM REPORT ISSUED				
Ian Levine ,					
FIRM NAME		STREET ADDRESS	2		
AMD Medicom	nc. (GRANBY PLANT)	209 Rue	York		
CITY, STATE, ZIP CODE, COUN		TYPE ESTABLISHMENT INSPECTED			
Granby, Quebe	ec, J2G2B9	Manufact	turer		
observations, and do observation, or have action with the FDA questions, please con	bservations made by the FDA represent not represent a final Agency determin implemented, or plan to implement, c representative(s) during the inspection tact FDA at the phone number and ad	nation regarding your co orrective action in respo n or submit this informa dress above.	mpliance. If you have an ob nse to an observation, you n tion to FDA at the address a	jection regarding an may discuss the objection o ibove. If you have any	
	oted in this Form FDA-483 are no for conducting internal self-audits				
preventive action Examples inclue Non-conforman		address the root ca dated 1/8/2016, w	use of the identified hich was (b) (4)		
	The corrective. . There was no signed and dated on 1/11/20	o documentation th	the (b) (4)	was implemented	
	b) (4) , which was opened y. The corrective/preventive ntation that the ^(b) (4)	action was to (b) (complaints of materi 4) ne CAPA was closed	. There	
CAPA-(b) (4) gets blocked du	, which was opened due to ring the ^{(b) (4)} process. The				
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Frank J Marciniak, Inv Device Cadre	vestigator - De	dicated X	DATE ISSUED 2/9/2017	

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION					
DISTRICT ADDRESS AND PHON 10903 New Han	ne NUMBER Noshire Avenue		DATE(S) OF INSPECTION 2/6/2017-2/9/2017		
Silver Spring		FEI NUMBER 3000164103			
NAME AND TITLE OF INDIVIDUA	INDIVIDUAL TO WHOM REPORT ISSUED				
Ian Levine ,	President				
AMD Medicom	.com Inc. (GRANBY PLANT) 209 Rue				
CITY, STATE, ZIP CODE, COUN Granby, Quebe					
(b) (4) There w	as no documentation that the action	was implemented. The C	CAPA was closed.		
Specifically, the	r record has not been maintained. e device master record for the ophtha production process specifications, qu		25-4 25-5 25-5 25-5 25-5		
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)					
Observation 1: Observation 2: Observation 3:	Annotations to Promised to correct within 3 Promised to correct within 3 Corrected and verified				
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Frank J Marciniak, Investiga Device Cadre	tor - Dedicated	DATE ISSUED 2/9/2017		
FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE INS	PECTIONAL OBSERVATIONS	PAGE 2 OF 2 PAGES		

DEPARTM	IENT OF HEALTH AND HUM FOOD AND DRUG ADMINISTRAT				
DISTRICT ADDRESS AND PHONE NUMBER		DATE(S) OF INSPECTION 2/13/2017-2/16/2017			
10903 New Hampshire Avenue					
Silver Spring, 20993 (301)594-4695 Fax:(301)594-4715		FEI NUMBER 3002772505			
(301/3)4-4035 Fax. (301/3)4-4/13					
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED					
Antoni Jauma , Managing Director					
FIRM NAME	STREET ADDRESS				
Diagnostic Grifols, S.A.		Fluvial, 24			
CITY, STATE, ZIP CODE, COUNTRY Parets Del Valles, Barcelona, 08					
This document lists observations made by the FDA n observations, and do not represent a final Agency de observation, or have implemented, or plan to implen action with the FDA representative(s) during the insp questions, please contact FDA at the phone number a	termination regarding your co nent, corrective action in respo pection or submit this informa	mpliance. If you have an objection nse to an observation, you may dis	regarding an cuss the objection or		
The observations noted in this Form FDA-483 firm is responsible for conducting internal self- requirements.					
DURING AN INSPECTION OF YOUR FIRM I OBSER OBSERVATION 1 An MDR report was not submitted with information that reasonably suggests th cause or contribute to a death or serious Specifically, your firm did not submit a becoming aware of the event. For example, Complaint # (b) (4) , was reported by your firm only on 12/0	ain 30 days of receiving at a marketed device h s injury if the malfunct n MDR report for all r dated 05/15/2015, invo	as malfunctioned and wou ion were to recur. eportable events within thi blved "(b) (4)	ld be likely to irty days of " This event		
OBSERVATION 2 Potential suppliers were not evaluated and selected based on their ability to meet specified requirements.					
SEE REVERSE ROY Baby, Investig	ator	2/15/ X Roy Baby	DATE ISSUED 2/16/2017		
		Roy Baby Investigator Signed by: Roy Baby -S	_		

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION				
DISTRICT ADDRESS AND PHON	e NUMBER Npshire Avenue	C	INSPECTION 2017-2/16/2017	
Silver Spring		FEI NUMBER	1	
(301)594-4695	5 Fax: (301) 594-4715	30027	3002772505	
NAME AND TITLE OF INDIVIDUA	AL TO WHOM REPORT ISSUED			
	, Managing Director			
Diagnostic G	cifols S A	STREET ADDRESS	1 24	
CITY, STATE, ZIP CODE, COUNT	gnostic Grifols, S.A. Passeig Fluvial, 24 TATE, ZIP CODE, COUNTRY TYPE ESTABLISHMENT INSPECTED			
Parets Del Va	alles, Barcelona, 08150Spain	Medical Device	Manufacturer	
Specifically vo	ur firm's Supplier Management proc	redure (b) (4)	dated	11/18/2016,
requires (b) (4)	ur innis supprer trangement proc		However, your firm	- the second second second
	ment the evaluations of your compo			did liot
suppliers.	ment the evaluations of your compo	ment suppliers, inc		
suppliers.				
For example	2:			
A Vour fir	m has been using an (b) (4)		ainea 2011 Vo	ur firm did not
	-		, since 2011. Yo	
	nt the evaluation and selection of this	10 m	In addition, your n	
follow y	our procedure in auditing the suppli	er.		
B. Your fir	m has been using an (b) (4)	supplier, (k	(4) , since 2	2008. Your
firm did	not document the evaluation and se	lection of this com	ponent supplier.	
(2001) (20010) (200		(1-) (4)	-	
C. Your fir		plier, (b) (4)		
	, since 2008. Your firm did not doo	cument the evaluation	ion and selection of	this
compone	ent supplier.			
OBSERVATION 3				
Sampling plans	are not based on valid statistical rat	ionale.		
Specifically, you	ur firm did not provide any statistic	l rationale to justi	fy the compline mot	had for
And a second second second second	ur firm did not provide any statistic:	ai rationale to justi	ry me sampning met	liou ioi
meoning raw ii	naterial inspection.			
Ean arrange la				
For example,				
A. Your incoming inspection for ^(b) ⁽⁴⁾ requires only a ^(b) ⁽⁴⁾				
	EMPLOYEE(S) SIGNATURE			DATE ISSUED
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			Investigator Signed by: Roy Baby -S	
FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE INS	PECTIONAL OBSERVA	TIONS	PAGE 2 OF 3 PAGES

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Silver Spring)17-2/16/20	1/		
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	, Managing Director					
FIRM NAME		STREET ADDRESS				
Diagnostic Gr		Passeig I		24		
(Participation in this is the second s	alles, Barcelona, 08150Spain			Manufacture	r	
(b) (4)	. The lot si	ze for a rec	ent shipm	ent was (b) (4)	
P Vouring	coming ingression for (b) (4) require	a_{a} only (b) (4	.)			
	coming inspection for ^{(b) (4)} require		· 8:			•
The batc	h size for a recent shipment was ^(b)	(-)				
	Annotations	o Observat	tions			
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Observation 2 :	Promised to correct					
Observation 3:	Promised to correct					
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OF THIS PAGE				Roy Baby		
				Investigator Signed by: Roy Baby -S		
FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE INS	PECTIONAL O	BSERVATIO	ONS		PAGE 3 OF 3 PAGES