See Instructions for OMB Statement. FORM APPROVED:OMB No.0910-0543. Expiration Date: 6/30/2020

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE

FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-RASED PRODUCTS (HCT/Ps)

1. REGISTRATION NUMBER	2. REASON FOR SUBMISSION
(FDA Establishment Identifier)	a. INITIAL REGISTRATION / LISTING
FEI: 0001038671	b. X ANNUAL REGISTRATION / LISTIN
· Li. 0001036071	c CHANGE IN INFORMATION

VALIDATION--FOR FDA USE ONLY
VALIDATED BY FDA:29-NOV-2017
DISTRICT: Florida
PRINTED BY FDA:27-JAN-2018

AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/P (See reverse side for instructions)		FEI: 00010)380/1				_	NGE IN IN	NFORMA	TION	PR	INTED	BY FDA:2	7-JAN-2018
		d. INACTIVE PRODUCT INFORMATION							003	≤ ₹2.5	₩₽₽			
3. OTHER FDA REGISTRATIONS					OF HC	T / Ps					표명.	E DIC	REGU RUG	
a. BLOOD FDA 2830 NO.	10. ESTABLISHMENT FUNCTIO		NS AND TYPES OF HCT / Ps Establishment Functions								11. HCT/Ps DESCRIBED IN 21 CFR 1271.10	PATE	JGIC ST/P	14. PROPRIETARY
	Types of	UCT / De									1 5 E	12. HCT/Ps REGULATED AS MEDICAL DEVICES	A B	NAME(S)
b. DEVICES FDA 2891 NO. <u>FEI: 0001038671</u>	Types of	1101775	Recove	r Screen	Test	Package	Process	Store	Label	Distribute	21	S	13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS	
c. DRUG FDA 2656 NO														
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code)	a. Bone					X	X	X	X	X	X	X		***See full text on next page
Exactech, Inc.	b. Cartilage													
2320 NW 66th Court Gainesville, Florida 32653	c. Cornea													
	d. Dura Mater													
a. PHONE 352-377-1140 EXT 4698	e. Embryo	☐ SIP ☐ Directed ☐ Anonymous												
b. SATELLITE RECOVERY ESTABLISHMENT MANUFACTURING ESTABLISHMENT FEI NO.	f. Fascia													
cTESTING FOR MICRO-ORGANISMS ONLY 5. ENTER CORRECTIONS TO ITEM 4	g. Heart Valve													
	h. Ligament													
MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code)	i. Oocyte	SIP Directed Anonymous												
Exactech, Inc. Attn: Ann M. Kelly, CTBS	j. Pericardium													
2320 NW 66th Court Gainesville, Florida 32653	k. Peripheral Blood Stem	Autologous Family Related Allogeneic												
	I. Sclera													
a. PHONE 352-377-1140 EXT 4698	m. Semen	SIP Directed Anonymous												
7. ENTER CORRECTIONS TO ITEM 6 b. PHONE	n. Skin													
	o. Somatic Cell Therapy Products	Autologous Family Related Allogeneic												
8. U.S. AGENT	p. Tendon													
	q. Umbilical Cord Blood	Autologous Family Related Allogeneic												
a. E-MAIL	r. Vascular Graft													
9. REPORTING OFFICIAL'S SIGNATURE	S.													
a TVDED NAME. And M. Wolle, CTDS	t.													
a. TYPED NAME Ann M. Kelly, CTBS	u.													
b. E-MAIL ann.kelly@exac.com	v.		1							+				
c. TITLE Tissue Bank Director d. DATE 29-NOV-2017	v.		1	1			1	1		1	1	1		

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
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FEI: 0001038671

(See reverse side for instructions)	
ADDITIONAL INFORMATION:	
Proprietary Names: Optecure, Optecure+ccc, Entice, Entice+, RTI Opteform	
Proprietary Name(s):	

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