See Instructions for OMB Statement. FORM APPROVED:OMB No.0910-0543. Expiration Date: 3/31/2017

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE

FOOD AND DRUG ADMINISTRATION

1. REGISTRATION NUMBER	
(FDA Establishment Identifier)	

b. X ANNUAL REGISTRATION / LISTING DISTRICT: Detroit

2. REASON FOR SUBMISSION

2. REASON FOR SUBMISSION VALIDATION.-FOR FDA USE ONLY
a. INITIAL REGISTRATION / LISTING VALIDATED BY FDA:16-DEC-2014

ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps (See reverse side for instructions)						c. [CHAN		IFORMA ⁻	ΓΙΟΝ	PR	RINTED BY FDA:22-DEC-2014			
PART I - ESTABLISHMENT INFORMATION	PART II - PR	PART II - PRODUCT INFORMATION									유무크	≦R12	B223		
3. OTHER FDA REGISTRATIONS		10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps 기계													
a. BLOOD FDA 2830 NO	Es					tablishment Functions						PAR	13. HCT/Ps REGULATED / DRUGS OR BIOLOGICAL I	14. PROPRIETARY NAME(S)	
b. DEVICES FDA 2891 NO.	Types of HCT / Ps		Recover	Screen	Test	Package	Process	Store	Label	Distribute	11. HCT/Ps DESCRIBED IN 21 CFR 1271.10	12. HCT/Ps REGULATED AS MEDICAL DEVICES	D AS	NAME(O)	
c. DRUG FDA 2656 NO													S		
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code)	a. Bone														
Cook General BioTechnology, LLC	b. Cartilage														
1102 Indiana Ave. Indianapolis, Indiana 46202	c. Cornea														
a. PHONE 317-917-3450 EXT	d. Dura Mater														
	e. Embryo	SIP Directed Anonymous													
b. SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO.	f. Fascia	·													
c TESTING 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													
Cook General BioTechnology, LLC Attn: Amelia E. Hufford, PhD	j. Pericardium														
1102 Indiana Ave. Indianapolis, Indiana 46202	k. Peripheral Blood Stem	■ Autologous □ Family Related □ Allogeneic				X		X	X	X	X				
	I. Sclera														
a. PHONE 317-917-3450 EXT 7. ENTER CORRECTIONS TO ITEM 6	m. Semen	X SIP X Directed X Anonymous				X		X	X	X	X				
b. PHONE	n. Skin														
	Therapy	X Autologous X Family Related X Allogeneic	x	X		X	X	X	X	X	X		X		
8. U.S. AGENT	p. Tendon														
	q. Umbilical Cord Blood	X Autologous X Family Related Allogeneic	X	X		X	X	X	x	X	X				
a. E-MAIL	r. Vascular Graft														
9. REPORTING OFFICIAL'S SIGNATURE	s. Placenta		X	X		X	X	X	X	X	X				
a. TYPED NAME Amelia E. Hufford, PhD	t. Tooth Pulp		X			X	X	X	X	X	X				
b. E-MAIL Amelia. Hufford@cookgbt.com	u. Umbilical Cord		X	X		X	X	X	X	X	X				
c. TITLE Regulatory Scientist d. DATE 15-DEC-2014	v.														

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-BASED PRODUCTS (HCT/Ps)

(See reverse side for instructions)

1. REGISTRATION NUMBER (FDA Establishment Identifier)

FEI: 3004976934

ADDITIONAL INFORMATION:

Somatic cell therapy products include mesenchymal stem cells (MSC) from multiple sources, for example, cord tissue MSC, Dental Pulp MSC and bone marrow MSC. Somatic cell therapy products are released or will be released under IND, as required.

Proprietary Name(s):

FORM FDA - 3356 (5/14)