

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION <b>ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS,  TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS  DESCRIBED IN 21 CFR 1271.10</b>	<b>FEI:</b> 3004976934	<b>Other FDA Registrations:</b> <b>Blood:</b> <b>Devices:</b> <b>Drugs:</b>	Reason For Last Submission: Annual Registration/Listing Last Annual Registration Year: 2019 Last Registration Receipt Date: 12/17/2018 Summary Report Print Date: 12/19/2018
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<b>Legal Name and Location:</b> Cook General BioTechnology, LLC 1102 Indiana Ave.  Indianapolis, Indiana 46202 USA Phone: 317-917-3450 <b>Ext.:</b>	<b>Reporting Official:</b> Andrea D Swingle, Regulatory & Clinical Scientist 1102 Indiana Ave. Indianapolis, Indiana 46202 USA Phone: 317-917-3450 Ext. Andrea.Swingle@CookRegentec.com	<b>Satellite Recovery Establishment:</b> No <b>Parent Manufacturing Establishment FEI No.:</b> <b>Testing For Micro-Organisms Only:</b> No  Note: FDA acceptance of an establishment registration and HCT/P listing does not constitute a determination that an establishment is in compliance with applicable rules and regulations or that the HCT/P is licensed or approved by FDA (21 CFR 1271.27(b)).
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HCT/P(s)	Donor Type(s)	Establishment Functions								Date of Discontinuance	Date of Resumption	Proprietary Name(s)
		Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute			
Amniotic Membrane												
Blood Vessel												
Bone												
Cardiac Tissue - non-valved												
Cartilage												
Cornea												
Dura Mater												
Embryo												
Fascia												
Heart Valve												
HPC Apheresis	Autologous							X	X			
HPC Cord Blood	Autologous, Family Related							X	X			
Ligament												
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium												
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera												
Semen	Anonymous, Directed, SIP							X	X			
Skin												
Tendon												
Testicular Tissue												
Tooth Pulp								X	X			
Umbilical Cord Tissue								X	X			

**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):**