

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> 1000513310	<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: 12/13/2018 Summary Report Print Date: 12/19/2018
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<b>Legal Name and Location:</b> KeraLink - New England 300 Bear Hill Road 2nd Floor  Waltham, Massachusetts 02451 USA Phone: 888-701-8078 <b>Ext.:</b>	<b>Reporting Official:</b> Connie J Jones, VP, Quality, Regulatory, Compliance 5520 Research Park Drive Suite 400 Baltimore, Maryland 21228 USA Phone: 770-855-4368 Ext. cjones@keralink.org	<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			X		X	X	X	X	X			VisionGraft
Dura Mater												
Embryo												
Fascia												
Heart Valve												
HPC Apheresis												
HPC Cord Blood												
Ligament												
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium												
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera			X					X				
Semen												
Skin												
Tendon												
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

**Additional Information:** No additional information provided.

**Proprietary Name(s):**