

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> 3014298539	<b>Other FDA Registrations:</b> <b>Blood:</b> <b>Devices:</b> FEI: 3014211822 <b>Drugs:</b>	Reason For Last Submission: Annual Registration/Listing Last Annual Registration Year: 2025 Last Registration Receipt Date: 11/26/2024 Summary Report Print Date: 12/05/2024
--	------------------------	--	---

<b>Legal Name and Location:</b>  Berkeley Advanced Biomaterials, LLC 2800 Seventh Street   Berkeley, California 94710 USA  Phone: 510-883-0500 <b>Ext.:</b>	<b>Reporting Official:</b> Mesfin W Mengesha, Chief Executive Officer 2800 Seventh Street Berkeley, California 94710 USA Phone: 510-883-0500 Ext. mmengesha@ostetic.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)).
--	---	--

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					X	X	X	X	X			
Blood Vessel												
Bone					X	X	X	X	X			***See full text on next page.
Cardiac Tissue - non-valved												
Cartilage												
Cornea												
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												
Semen												
Skin					X		X	X	X			
Tendon												
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

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

<b>Proprietary Name(s):</b>	Bone	Vanilla Cortical Ground Bone, Vanilla Cancellous/Cortical Mix, Vanilla Cancellous Bone, Allograft Cancellous Bone Chips 4-10mm, Cancellous Bone, Ground Cortical Bone, Demineralized Cortical Fiber Strip, Demineralized Cancellous Bone, R-GENIN Putty, R-GENIN Strip, H-GENIN Strip, H-GENIN Putty, H-GENIN Crush-Mix, DBM Powder, DBM Crush-Mix, DBM Gel, Advanced Mineralized Graft [AMG] Fiber Strip, Advanced Mineralized Graft [AMG] Fiber, Structural Allograft Cervical Spacer, Augmentation Gel
-----------------------------	------	---

FEI: 3014298539

Legal Name:

Berkeley Advanced Biomaterials, LLC