

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  
 DESCRIBED IN 21 CFR 1271.10**

FEI: 0002242450

**Other FDA Registrations:**  
**Blood:**  
**Devices:**FEI: 0002242450  
**Drugs:**

Reason For Last Submission: Annual Registration/Listing  
 Last Annual Registration Year: 2026  
 Last Registration Receipt Date: 12/11/2025  
 Summary Report Print Date: 12/15/2025

**Legal Name and Location:**

Katena Products, Inc,  
 4 Middlebury Boulevard  
 Unit #1

Randolph, New Jersey 07869  
 USA

Phone: 973-957-3509

Ext.:

**Reporting Official:**

Alex Castillo, Vice President, QA & RA  
 4 Middlebury Blvd, Unit 1  
 Randolph, New Jersey 07869  
 USA  
 Phone: 619-617-8100 Ext.  
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**Satellite Recovery Establishment:** No  
**Parent Manufacturing Establishment FEI No.:**  
**Testing For Micro-Organisms Only:** 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			Ambio2, Ambio5, AmbioDisk
Blood Vessel												
Bone												
Cardiac Tissue - non-valved												
Cartilage												
Cornea							X		X			Tutoplast
Dura Mater												
Embryo												
Fascia							X		X			Tutoplast
Heart Valve												
HPC Apheresis												
HPC Cord Blood												
Ligament												
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium							X		X			Tutoplast
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera							X		X			Tutoplast
Semen												
Skin												
Tendon												
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

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

**Proprietary Name(s):**

FEI: 0002242450

Legal Name:

Katena Products, Inc,