

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> 3008650117	<b>Other FDA Registrations:</b> <b>Blood:</b> <b>Devices:</b> FEI: 3008650117 <b>Drugs:</b>	Reason For Last Submission: Annual Registration/Listing Last Annual Registration Year: 2025 Last Registration Receipt Date: 12/18/2024 Summary Report Print Date: 12/20/2024
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<b>Legal Name and Location:</b>  Paragon 28 , Inc. 14445 Grasslands Dr.  Englewood, Colorado 80112 USA  Phone: 888-728-1888 <b>Ext.:</b>	<b>Reporting Official:</b> Edward Wells-Spicer, Regulatory Affairs Specialist 14445 Grasslands Dr. Englewood, Colorado 80112 USA Phone: 855-786-2828 Ext. ewspicer@paragon28.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							X		X			Pro3
Blood Vessel												
Bone							X		X			Preserve, V92, BEAST
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			Paraderm
Tendon												
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue							X		X			Pro3

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

**Proprietary Name(s):**

FEI: 3008650117

Legal Name:

Paragon 28 , Inc.