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

Ext.:

FEI: 3003140045

Reporting Official:

Other FDA Registrations:

Blood: Devices: Drugs: Reason For Last Submission: Annual Registration/Listing

Last Annual Registration Year: 2023
Last Registration Receipt Date: 11/18/2022
Summary Report Print Date: 12/01/2022

Legal Name and Location:

Genetics & IVF Institute 3015 Williams Drive 3rd Floor

Fairfax, Virginia 22031

Phone: 703-698-7355

USA

Megan Taylor, Document Administrator 3015 Williams Drive Attn: Sara Kraner

Fairfax, Virginia 22031 USA

Phone: 800-338-8407 Ext. mtaylor@givf.com

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)).

		Establishment Functions										
HCT/P(s)	Donor Type(s)	Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute	Date of Discontinuance	Date of Resumption	Proprietary Name(s)
Amniotic Membrane												
Blood Vessel												
Bone												
Cardiac Tissue - non-valved												
Cartilage												
Cornea												
Dura Mater												
Embryo	Anonymous, Directed, SIP		Х		Х	Х	Х	Х	Х			
Fascia												
Heart Valve												
HPC Apheresis												
HPC Cord Blood												
Ligament												
Nerve Tissue												
Oocyte	Anonymous, Directed, SIP	Х	Х		Х	Х	Х	Х	Х			
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium												
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera												
Semen	Anonymous, Directed, SIP						Х					
Skin												
Tendon												
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

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

Proprietary Name(s):

FEI: 3003140045 Legal Name: Genetics & IVF Institute