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: 3011125133

Reporting Official:

Other FDA Registrations:

Blood: Devices: Drugs:

Reason For Last Submission: Annual Registration/Listing

Last Annual Registration Year: 2024 Last Registration Receipt Date: 11/19/2023 Summary Report Print Date: 12/01/2023

Legal Name and Location:

California Fertility Experts-Hanabusa IVF 4910 Directors Place #150

Peter Fuzesi, Chief Operating Officer 4910 Directors Place #150 San Diego, California 92121

Phone: 858-381-3210 Ext. peter.fuzesi@hanabusaivf.com Satellite Recovery Establishment: No

Parent Manufacturing Establishment FEI No.:

Testing For Micro-Organisms Only:

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)).

San Diego, California 92121 USA

Phone: 858-480-5400 Ext.:

		<u>.</u>	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	X	Х			
Fascia												
Heart Valve												
HPC Apheresis												
HPC Cord Blood												
Ligament												
Nerve Tissue												
Oocyte	Anonymous, Directed, SIP	X	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	X	Х		Х	Х	Х	Х	Х			
Skin												
Tendon												
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Additional Information:	No additional information provided.
Additional information.	140 additional information provided.

Proprietary Name(s):

FEI: 3011125133 Legal Name: California Fertility Experts-Hanabusa IVF