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eHCTERS - Registration Information

Submitted Registration Information

This information has been submitted to the FDA
Please Remember Your Confirmation Number to Reference this registration submission

YOUR CONFIRMATION NUMBER IS: 68032

Please print this document and maintain as confirmation of your submission.
This application is no longer accessible using your pre-confirmation number.

FEI: 3011680766

Other FDA Registrations

- Blood
- Devices 3011680766
- Drug 3011680766

Reason for Submission

- Initial Registration/Listing
- Annual Registration/Listing
- Change in Information
- In-Activate Registration

Physical Location

Legal Name: Novex Innovations
 Street Address: 101 N Chestnut Street
 Suite 308
 City: Winston-Salem
 State: North Carolina
 Postal Code: 27101
 Country: UNITED STATES
 Phone: 336-231-6693 ext.

Reporting Official Information

First Name: Brandi
 Last Name: Shanahan
 Title: Director of Quality
 Phone: 336-231-6693 Ext.
 E-Mail Address: bshanahan@novexinnovations.com

Mailing Address of Reporting Official

Institution Name: Novex Innovations
 Street Address: 101 N Chestnut Street
 Suite 308
 City: Winston-Salem
 State: North Carolina
 Postal Code: 27101
 Country: UNITED STATES

HCT/P Listing Information

Types of HCT/Ps	HCT/Ps Described	Date of	Date of	Proprietary Names
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Pericardium									
Peripheral Blood Mononuclear Cells									
Peritoneal Membrane									
Sclera									
Semen									
Skin									
Tendon									
Testicular Tissue									
Tooth Pulp									
Umbilical Cord Tissue		<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

HCT/P Listing - Donor Information

Types of HCT/Ps	SIP	Directed	Anonymous	Autologous	Family Related
Embryo					
HPC Apheresis					
HPC Cord Blood					
Oocyte					
Peripheral Blood Mononuclear Cells					
Semen					

Additional Information

Currently accredited by AATB

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DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG ADMINISTRATION
 ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS,
 TISSUES AND CELLULAR AND TISSUE-BASED PRODUCTS (eHCTERS)

eHCTERS v02.13.04
 Updated 07/29/2024

OMB Control Number 0910-0543; Expiration Date 08/31/2026
 See [OMB Burden Statement](#)

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