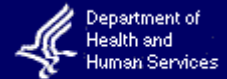




U.S. Food and Drug Administration



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eHCTERS - Registration Information

Submitted Registration Information

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YOUR CONFIRMATION NUMBER IS: 36946

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FEI: 3013188515

Other FDA Registrations

- Blood FDA 2830
 Devices FDA 2891 0010051435
 Drug FDA 2656

Reason for Submission

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

Physical Location

Legal Name: HealthLink International Inc.
Street Address: 3655 Knight Road
Suite 1-3
City: Memphis
State: Tennessee
Postal Code: 38118
Country: United States
Phone: 18773242837 ext.

Reporting Official Information

First Name: Richard
Last Name: Hughes
Title: Co-Founder, President
Phone: 919-349-1293 Ext.
E-Mail Address: rick.hughes@healthlinkeurope.com

Mailing Address of Reporting Official

Institution Name: HealthLink International, Inc.
Street Address: 211 E. Six Forks Road, Suite 209A
City: Raleigh
State: North Carolina
Postal Code: 27609
Country: United States

HCT/P Listing Information

	Types of HCT/P's	HCT/P's Described in 21 CFR 1271.10	HCT/P's Regulated as Medical Devices	HCT/P's Regulated as Drugs or Biological Drugs	Proprietary Names
a.	Bone	X			
b.	Cartilage	X			
c.	Cornea				

d.	Dura Mater	X			
e.	Embryo				
f.	Fascia	X			
g.	Heart Valve				
h.	Ligament	X			
i.	Oocyte				
j.	Pericardium	X			
k.	Peripheral Blood Stem Cells	X			
l.	Sclera				
m.	Semen				
n.	Skin	X			
o.	Somatic Cell Therapy Products	X			
p.	Tendon	X			
q.	Umbilical Cord Blood Stem Cells				
r.	Vascular Graft	X			
s.	Placenta	X			
t.	Amniotic Membrane	X			
u.	Amniotic Fluid	X			

HCT/P Listing - Function Information

	Types of HCT/P's	Recover	Screen	Test	Package	Process	Store	Label	Distribute
a.	Bone						<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
b.	Cartilage						<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
c.	Cornea								
d.	Dura Mater						<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
e.	Embryo								
f.	Fascia						<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
g.	Heart Valve								
h.	Ligament						<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
i.	Oocyte								
j.	Pericardium						<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
k.	Peripheral Blood Stem Cells						<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
l.	Sclera								
m.	Semen								
n.	Skin						<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
o.	Somatic Cell Therapy Products						<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
p.	Tendon						<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
q.	Umbilical Cord Blood Stem Cells								
r.	Vascular Graft						<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
s.	Placenta						<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
t.	Amniotic Membrane						<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
u.	Amniotic Fluid						<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

HCT/P Listing - Donor Information

	Types of HCT/P's	SIP	Directed	Anonymous	Autologous	Family Related	Allogeneic
e.	Embryo						
i.	Oocyte						
k.	Peripheral Blood Stem Cells						<input checked="" type="checkbox"/>
m.	Semen						
o.	Somatic Cell Therapy Products						<input checked="" type="checkbox"/>
q.	Umbilical Cord Blood Stem Cells						

Select New Establishment

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Submitted Registration Information
TISSUES AND CELLULAR AND TISSUE-BASED PRODUCTS (eHCTERS)

eHCTERS v02.08.00
Updated 06/27/2014

FORM FDA - 3356 (5/14) FORM APPROVED:OMB No.0910-0543
Expiration Date: 3/31/2017

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