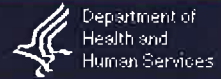




# U.S. Food and Drug Administration



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### HUMAN CELL AND TISSUE ESTABLISHMENT REGISTRATION - Public Query Establishment Details

#### Establishment Name and Location

Current Status: Registered  
 Last Annual Registration Year: 2009  
 FDA Establishment Identifier (FEI): 3001503333  
 Establishment Name: IsoTis OrthoBiologics, Inc.  
 Address: 2 Goodyear, Suite A  
 City: Irvine  
 State: California  
 Zip: 92618  
 Country: United States  
 Phone: 949-855-7168

#### Establishment Functions

	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"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
b.	Cartilage								
c.	Cornea								
d.	Dura Mater								
e.	Embryo								
f.	Fascia								
g.	Heart Valve								
h.	Ligament								
i.	Oocyte								
j.	Pericardium								
k.	Peripheral Blood Stem Cells								
l.	Sclera								
m.	Semen								
n.	Skin								
o.	Somatic Cell Therapy Products								
p.	Tendon								
q.	Umbilical Cord Blood Stem Cells								
r.	Vascular Graft								

#### Establishment HCT/P Listing

	HCT/P's Described	HCT/P's Regulated	HCT/P's Regulated as

	Types of HCT/P's	in 21 CFR 1271.10	as Medical Devices	Drugs or Biological Drugs	Proprietary Names
a.	Bone	X	X		See Additional Info
b.	Cartilage				
c.	Cornea				
d.	Dura Mater				
e.	Embryo				
f.	Fascia				
g.	Heart Valve				
h.	Ligament				
i.	Oocyte				
j.	Pericardium				
k.	Peripheral Blood Stem Cells				
l.	Sclera				
m.	Semen				
n.	Skin				
o.	Somatic Cell Therapy Products				
p.	Tendon				
q.	Umbilical Cord Blood Stem Cells				
r.	Vascular Graft				

HCT/P Listing - Donor Information

	Types of HCT/P's	SIP	Directed	Anonymous	Autologous	Family Related	Allogenic
e.	Embryo						
i.	Oocyte						
k.	Peripheral Blood Stem Cells						
m.	Semen						
o.	Somatic Cell Therapy Products						
q.	Umbilical Cord Blood Stem Cells						

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