U.S. Food and Drug Administration
Department of Health and Human Services
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

FEI: 3010125671 **Pre-Confirmation Number:** 40370
Legal Name: Harbinger Medical Group L.L.C.dba Tides Medical **Todays Date:** 12/27/2017

Registration | Address | Reporting Official | U.S. Agent | HCT/P Listing | Function | Donor | Additional Info | Report | Save

eHCTERS - Registration Information

Preview your Registration Information

THIS INFORMATION HAS NOT BEEN SUBMITTED TO THE FDA
PLEASE REVIEW YOUR REGISTRATION INFORMATION
PRESS THE "SUBMIT TO FDA" BUTTON at the bottom of the page TO CONTINUE

Note: The FORM FDA - 3356 data has been saved but not submitted to the FDA. Unfinished forms are accessible for 30 days. If the registration is not completed and submitted in that period, data will be archived and will not be accessible.

Your Pre-Confirmation Number is 40370
Enter this number on the main screen to access your unfinished submission.
FEI: 3010125671

Other FDA Registrations

- ☐ Blood FDA 2830
- ☐ Devices FDA 2891
- ☐ Drug FDA 2656

Reason for Submission

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

Physical Location

Legal Name:	Harbinger Medical Group L.L.C.dba Tides Medical
Street Address:	1819 West Pinhook RD
	Suite 109
City:	Lafayette
State:	Louisiana
Postal Code:	70508
Country:	United States
Phone:	337-322-4194 ext.
Satellite Recovery Establishment:	Yes
Manufacturing Establishment FEI Number:	3012622594

Reporting Official Information

First Name:	Joe
Last Name:	Spell
Title:	CEO
Phone:	337-322-4194 Ext.
E-Mail Address:	jspell@tidesmedical.com

Mailing Address of Reporting Official

Institution Name:	Tides Medical
Street Address:	1819 West Pinhook RD

Suite 109
City: Lafayette
State: Louisiana
Postal Code: 70508
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			Bowline,Hitch, Trefoil
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				
s.	Amniotic Membrane	X			Lanyard, AmnioJect,AmnioHeal,AmnioHeal Plus,Artacent, Artacent Flex, Artacent Wound, Reims Dual Layer Amnion,

HCT/P Listing - Function Information

	Types of HCT/P's	Recover	Screen	Test	Package	Process	Store	Label	Distribute
a.	Bone						☑		☑
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								
s.	Amniotic Membrane						☑		☑

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						
m.	Semen						
o.	Somatic Cell Therapy Products						
q.	Umbilical Cord Blood Stem Cells						

Additional Information

Additional products: Artacent AC powder, Artacent AC Amnion Chorion

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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 v02.08.00
Updated 06/27/2014

FORM FDA - 3356 (7/17) FORM APPROVED:OMB No.0910-0543
Expiration Date: 6/30/2020