### 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**

Ext.:

FEI: 3010125671

Other FDA Registrations: Blood: Devices:

Drugs:

Reason For Last Submission: Annual Registration/Listing

Last Annual Registration Year: 2023 Last Registration Receipt Date: 11/21/2022 Summary Report Print Date: 12/01/2022

No

Legal Name and Location:

Harbinger Medical Group L.L.C.dba Tides Medical

1819 West Pinhook Rd

Suite 206

Lafayette, Louisiana 70508

USA

Phone: 337-326-0625

Reporting Official:

Benjamin Kimball, VP Quality & Regulatory Affairs

1819 West Pinhook Rd

Suite 206

Lafayette, Louisiana 70508

Phone: 337-326-0625 Ext. 141 bkimball@tidesmedical.com

Satellite Recovery Establishment:

Parent Manufacturing Establishment FEI No.:

Testing For Micro-Organisms Only: No

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)).

		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			Х				Х		Х			***See full text on next page.
Blood Vessel												
Bone							Х		Х			Bowline,Hitch
Cardiac Tissue - non-valved												
Cartilage												
Cornea												
Dura Mater												
Embryo												
Fascia												
Heart Valve												
HPC Apheresis												
HPC Cord Blood												
Ligament												
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium												
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera												
Semen												
Skin												
Tendon												
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

FEI:

3010125671

Legal Name:

Additional Informatio	on: No additional information provided.	
Proprietary Name(s):	Amniotic Membrane	Artacent AC, AmnioHeal Plus, Artacent Flex, Artacent Wound, Artacent Ocular, SteriMend, Artacent Connect

Legal Name: Harbinger Medical Group L.L.C.dba Tides Medical FEI: 3010125671

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# FOOD AND DRUG ADMINISTRATION

ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS **DESCRIBED IN 21 CFR 1271.10** 

Ext.:

FEI: 3012622594

Other FDA Registrations:

Blood: Devices: Drugs:

Reason For Last Submission: Annual Registration/Listing

Last Annual Registration Year: 2023 Last Registration Receipt Date: 11/21/2022 Summary Report Print Date: 12/01/2022

Legal Name and Location:

Harbinger Medical Group L.L.C dba Tides Medical

605 Kaliste Saloom Road

Suite H

Lafayette, Louisiana 70508

USA

Phone: 888-494-4441

Reporting Official:

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Lafayette, Louisiana 70508

Phone: 337-326-0625 Ext. 141 bkimball@tidesmedical.com

Satellite Recovery Establishment: Yes

Parent Manufacturing Establishment FEI No.: 3010125671

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)).

		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		Х	Х		Х	Х	х	Х		***See full text on next page.		
Blood Vessel												
Bone												
Cardiac Tissue - non-valved												
Cartilage												
Cornea												
Dura Mater												
Embryo												
Fascia												
Heart Valve												
HPC Apheresis												
HPC Cord Blood												
Ligament												
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium												
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera												
Semen												
Skin												
Tendon												
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Additional Informatio	on: No additional information provided.	
Proprietary Name(s):	Amniotic Membrane	Artacent AC, AmnioHeal Plus, Artacent Flex, Artacent Wound, Artacent Ocular, SteriMend, Amniovant-G

Legal Name: Harbinger Medical Group L.L.C dba Tides Medical FEI: 3012622594