

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**

FEI: 3007953176

Other FDA Registrations:

Blood:

Devices:

Drugs:

Reason For Last Submission: Annual Registration/Listing
Last Annual Registration Year: 2021
Last Registration Receipt Date: 12/11/2020
Summary Report Print Date: 12/14/2020

Legal Name and Location:

LifeCell International Pvt. Ltd.
26, Vandalur Kelambakkam Main Road
Keelakottaiyur

Chennai, 600127
INDIA

Phone: 914442935353

Ext.:

Reporting Official:

Pallavi Misra, SVP CQA & RA
26, Vandalur Kelambakkam Main Road
Keelakottaiyur
Chennai, 600127
INDIA
Phone: 914442935353 Ext. 205
pallavi.a@lifecell.in

Satellite Recovery Establishment:

No

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)	Establishment Functions								Date of Discontinuance	Date of Resumption	Proprietary Name(s)
		Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute			
Amniotic Membrane		X	X	X	X	X	X	X	X			AmchoPlast
Blood Vessel												
Bone												
Cardiac Tissue - non-valved												
Cartilage												
Cornea												
Dura Mater												
Embryo												
Fascia												
Heart Valve												
HPC Apheresis												
HPC Cord Blood	Autologous, Family Related	X	X	X	X	X	X	X	X			
Ligament												
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium												
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera												
Semen	Directed, SIP			X	X	X	X	X	X			
Skin												
Tendon												
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Additional Information: AmchoPlast is Sterile Dehydrated Human Amnion- Chorion Allograft

Proprietary Name(s):

For Non U.S. Establishments Only:

U.S. Agent(s):

Name and Organization	Address	Phone and Email
Om P. Sharma, Consultant LifeCell International Pvt. Ltd.	6111 Lone Oak Drive, Bethesda, Maryland, USA 20817	202-460-4248 om_s@yahoo.com

Importer(s):

Name and Organization	Address	Phone and Email
-----------------------	---------	-----------------

FEI: 3007953176

Legal Name:

LifeCell International Pvt. Ltd.