

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: 3007499718	Other FDA Registrations: Blood: Devices: FEI: 3010097171 Drugs:	Reason For Last Submission: Annual Registration/Listing Last Annual Registration Year: 2023 Last Registration Receipt Date: 01/04/2023 Summary Report Print Date: 01/05/2023
--	------------------------	--	---

Legal Name and Location: Millstone Medical Outsourcing 8836 Polk Lane Suite 100 Olive Branch, Mississippi 38654 USA Phone: 508-679-8384 Ext.:	Reporting Official: Kelly J Lucenti, President 580 Commerce Drive Fall River, Massachusetts 02720 USA Phone: 508-679-8384 Ext. 2026 klucenti@millstonemedical.com	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)).
---	--	--

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

Additional Information: No additional information provided.

Proprietary Name(s): Amniotic Membrane	BioFix; Amniofix; CTM Thin; CTM Thick; CTM Flow; CTM Boost; CTM Paste; CTM Powder; Amnioflo; Flower AmnioPatch; FlowerPatch; AMNIOGRAFT; AMNIOGUARD; CLARIX 100; CLARIX CORD; CLARIX FLO; NEOX 100; NEOX CORD; NEOX FLO; NEOX RT; TAG- Triple Layer Amniotic Graft
Bone	Osteoamp; Purebone; Exponent; Allograft Bone Wedge; SeaSpine Capistrano Cervical Spacer; SeaSpine PLIF Allograft; SeaSpine Compressible Bone Matrix; SeaSpine Cervical Allograft; Laminoplasty Cortical Allograft; LESBiologics; DBMForm; FacetFuse; Allo-Span; Allogenix DBM; Bonus CC Matrix; Bonus II DMB; Cellentra Advanced Allograft; EquivaBone; FiberStack DBM; Fortis ALIF, Composite, Cortical, PLIF, TLIF; Indux Cortical or Cancellous; InterGro DBM; PrimaGen Advanced Allograft; Osteostim Composite; Cortical, ALIF, PLIF; StaGraft Cancellous; StaGraft DBM; StaGraft Fiber; Trinnect; Puros; Puros-S; Fortitude; Bonus Triad; Copios; FIBERFORM; FIBER BOAT; FIBER ANCHOR; FIBER BULLETS; FIBERFORM+; FIBERFORM SYRINGE; FIBERFORM, OSTEOAMP SELECT Flowable, FlowerGRAFT; FibreX Demineralized Bone Fibers; Bigfoot; BioAdapt; BioReady; BioSet; Elemax; FIBER BAGS
Skin	HuMend; DermaSpan; DermaSpan Mesh; FlowerDerm
Umbilical Cord Tissue	CTM Thin; CTM Thick; CTM Flow; CTM Boost; CTM Paste; CTM Powder; CTM Flow LV

FEI: 3007499718

Legal Name:

Millstone Medical Outsourcing