DRLM Home (mainMenu.htm)

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Annual Registration Successful

Facility: ORGANOGENESIS INC., CANTON, Massachusetts, UNITED STATES

You have successfully updated your registration and listing information for 2025.

Your registration will be valid through Dec 31, 2025.

Be sure to print this page for your records.

Facility Information

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Facility URL:

Other Business Trade Name(s):

Establishment located on a campus:

The next registration renewal period is October 1 - December 31, 2025.

Registering your facility and listing devices does not, in any way, constitute FDA approval of your facility or devices.

You may contact the FDA with any questions at reglist@cdrh.fda.gov.

The Owner/Operator Number for this Registration is: 9008375.

Registration Number: 1221816 Initial Importer: N Facility Name: ORGANOGENESIS INC. Legal Name: Address: 150 DAN RD., CANTON, Massachusetts, 02021, UNITED STATES DUNS Number: Foreign Trade Zone:

Owner/Operator Information

Owner/Operator Number:

9008375

Contact Name: Patrick R Bilbo

Company:

ORGANOGENESIS INC.

Address: 150 Dan Road, --

Canton, MASSACHUSETTS, 02021, UNITED ST

ATES

Telephone: 781 - 4011155

Fax:

781 - 4011280

E-mail: Regulatory@organo.com

DUNS Number: 152165817

Official Correspondent Information

Contact Name: Patrick R Bilbo

Company:

ORGANOGENESIS INC.

Address: 150 Dan Road, --

Canton, MASSACHUSETTS, 02021, UNITED ST

ATES

Telephone: 781 - 4011155

Fax:

781 - 4011280

E-mail: Regulatory@organo.com

DUNS Number: 152165817

Device Listings

Listing Premarket Number Submission Number	Premarket Submission Type	Product Code(s)	Device Name(s)	Activities
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D459427		510(k) exempt	HTF	CURETTE	Complaint File Establishment Specification Developer
D287691	BP960700		MGR	Dressing, wound and burn, interactive	Manufacturer
D236167	K011026		KGN	Wound dressing with animal-derived material(s)	Manufacturer
D236168	K051647		FRO	Dressing, wound, drug	Manufacturer
D258455	BP953200		PFC	Cultured human cell skin dressing	Manufacturer
D015297	K042809		FTM	Mesh, surgical	Manufacturer
D213416	BP003600		PFC	Cultured human cell skin dressing	Manufacturer
D477558	K220317		KGN	Wound dressing with animal-derived material(s)	Manufacturer Complaint File Establishment

Date of Initial Registration: 1993-11-23 12:05:37.0