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# Annual Registration Successful

Facility: ORGANOGENESIS INC., Saint Petersburg, Florida, UNITED STATES

You have successfully updated your registration and listing information for 2026.

Your registration will be valid through Dec 31, 2026.

Be sure to print this page for your records.

The next registration renewal period is October 1 - December 31, 2026.

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.

#### **Facility Information**

Registration Number: 3012100095

Initial Importer:

Facility Name: ORGANOGENESIS INC.

Legal Name:

Address: 12495 34th Street North, Suite D

Saint Petersburg, Florida, 33716, UNITED STATES

DUNS Number: 079896008

Foreign Trade Zone: N

Facility URL:

Other Business Trade Name(s): Establishment located on a

campus:

## **Owner/Operator Information**

Owner/Operator Number: 9008375

Contact Name: Patrick R Bilbo

Company: ORGANOGENESIS INC.

Address: 150 Dan Road, --

Canton, MASSACHUSETTS, 02021, UNITED STATES

Telephone: 781 - 4792227 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 STATES

Telephone: 781 - 4792227 Fax: 781 - 4011280

E-mail: Regulatory@organo.com

**DUNS Number:** 152165817

## **Device Listings**

Listing Number	Premarket Submission Number	Premarket Submission Type	Product Code(s)	Device Name(s)	Activities
D464443	K152970		FRO	Dressing, wound, drug	Complaint File Establishment Repackager/Relabeler
D464254		510(k) exempt	NAD	Dressing, wound, occlusive	Repackager/Relabeler Complaint File Establishment

D464250		510(k) exempt	NAC	Dressing, wound, hydrophilic	Repackager/Relabele
					Complaint File Establishment
D458983	K122325		KGN	Wound dressing with animal-derived material(s)	Complaint File Establishment Repackager/Relabele
D458986	K011941		FRO	Dressing, wound, drug	Repackager/Relabele Complaint File Establishment
D458985	K060804		FRO	Dressing, wound, drug	Repackager/Relabele Complaint File Establishment
D484959	K910944		KGN	Wound dressing with animal-derived material(s)	Repackager/Relabele Complaint File Establishment
D464223		510(k) exempt	NAE	Dressing, wound, hydrogel without drug and/or biologic	Repackager/Relabele Complaint File Establishment
D458988		510(k) exempt	FQM	BANDAGE, ELASTIC	Complaint File Establishment Repackager/Relabele
D458991		510(k) exempt	NAB	Gauze / sponge,nonresorbable for external use	Complaint File Establishment Repackager/Relabele
D458990		510(k) exempt	KGX	Tape and bandage, adhesive	Repackager/Relabele Complaint File Establishment
D433711	K120181		FRO	Dressing, wound, drug	Repackager/Relabele Complaint File Establishment

Date of Initial Registration: 2021-01-19 15:45:23.0