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Annual Registration Successful

Facility: SCANTIBODIES LABORATORY, INC., SANTEE, California, UNITED STATES

You have successfully updated your registration and listing information for 2023.

Your registration will be valid through Dec 31, 2023.

Be sure to print this page for your records.

The next registration renewal period is October 1 - December 31, 2023.

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: 2020808.

Facility Information

Registration Number:

2020808

Initial Importer:

N

Facility Name:

SCANTIBODIES LABORATORY, INC.

Legal Name:

Address:

**9336 ABRAHAM WAY,
SANTEE, California, 92071, UNITED STATES**

DUNS Number:

Foreign Trade Zone:

N

Facility URL:

www.scantibodies.com

Other Business Trade Name(s):

Establishment located on a campus:

Owner/Operator Information

Owner/Operator Number:

2020808

Contact Name:

Julio C Padilla Gil

Company:

SCANTIBODIES LABORATORY INC.

Address:

**9336 Abraham Way, --
Santee, CALIFORNIA, 92071, UNITED STATES**

Telephone:

001 - 619 - 2589300 - 5203

Fax:

001 - 619 - 2589366

E-mail:

julio.padilla@scantibodies.com

DUNS Number:

087577680

Official Correspondent Information

Contact Name:

Mario Coronado

Company:

SCANTIBODIES LABORATORY INC.**Address:**

**9336 Abraham Way
Santee, CALIFORNIA, 92071, UNITED STATES**

Telephone:

1 - 619 - 2589300 - 5620

Fax:

1 - 619 - 2583974

E-mail:

mario.coronado@scantibodies.com

DUNS Number:**Device Listings**

Listing Number	Premarket Submission Number	Premarket Submission Type	Product Code(s)	Device Name(s)	Activities
D432888	K163713		LSR	REAGENT, BORRELIA SEROLOGICAL REAGENT	Contract Manufacturer
D432886	K173496		LSR	REAGENT, BORRELIA SEROLOGICAL REAGENT	Contract Manufacturer
D350751	K051810		CEW	RADIOIMMUNOASSAY, PARATHYROID HORMONE	Manufacturer Repackager/Relabeler
D218448	K051888		CEW	RADIOIMMUNOASSAY, PARATHYROID HORMONE	Manufacturer
D218447	K050748		CKG	RADIOIMMUNOASSAY, ACTH	Manufacturer
D465957	Enforcement Discretion		LQP	CAMPYLOBACTER SPP.	Contract Manufacturer Repackager/Relabeler

D432852		510(k) exempt	JRC	MICRO PIPETTE	Manufacturer
E323758	K021032		CKG	RADIOIMMUNOASSAY, ACTH	Manufacturer
D032013	K944788		CEW	RADIOIMMUNOASSAY, PARATHYROID HORMONE	Manufacturer
D426996	Enforcement Discretion		QMN	COVID-19 Multi-Analyte Antigen Device	Manufacturer Contract Manufacturer Repackager/Relabeler
D218452	K004038		CEW	RADIOIMMUNOASSAY, PARATHYROID HORMONE	Manufacturer
			JIS	Calibrator, primary	
			JJX	Single (specified) analyte controls (assayed and unassayed)	
D426558	Enforcement Discretion		QKP	Coronavirus antigen detection test system.	Repackager/Relabeler Manufacturer Contract Manufacturer
D032015	K954247		JJY	Multi-analyte controls, all kinds (assayed)	Manufacturer
D032016	K060578		JKR	RADIOIMMUNOASSAY, CALCITONIN	Manufacturer

Date of Initial Registration: 1987-01-28 00:00:00.0