

Department of Health

KATHY HOCHUL Governor **JAMES V. McDONALD, M.D., M.P.H.**Acting Commissioner

MEGAN E. BALDWINActing Executive Deputy Commissioner

April 19, 2023

Michael J. Bauer, M.D., FACP, CTBS Medical Director and Tissue Bank Director California Cryobank, LLC 11915 La Grange Avenue Los Angeles CA 90025-5213 FAC ID: 506

Dear Colleague,

Please find enclosed the provisional license certificate for tissue bank operation at the following location:

California Cryobank, LLC 950 Massachusetts Avenue Cambridge, MA 02139

The certificate is effective until the date indicated, or the issuance of a full license following an on-site survey of your facility. The certificate, which has been amended to reflect the change in Tissue Bank Director and Medical Director, replaces that issued January 26, 2022. The certificate must be posted conspicuously at the approved location. Your license is specific to this location; you must notify the Department of any changes in address.

You must submit a new application if you intend to expand your services or activities beyond those listed on this certificate. All tissue for clinical use must be procured, processed, stored, and distributed by tissue banks licensed by the Department for the relevant activities.

To remain in compliance with New York State regulations, you must also:

- Report any changes in director, medical director, and compliance officer within five days;
- Report any change in ownership of five percent or more within 30 days;
- Report any accidents in retrieval, testing, processing, storage, or distribution that may affect the safety of any product within seven calendar days of discovery.

Application forms and specifics of 10 NYCRR Part 52 and Subpart 58-5 regulations are available online at https://www.wadsworth.org/regulatory/tissue-resources. If you have any questions, please call (518) 485-5341, or e-mail tissue@health.ny.gov.

Sincerely,

Ďiane Sullivan, B.S., M.T. Tissue Bank Consultant Tissue Resources Program

Enclosure

NEW YORK STATE DEPARTMENT OF HEALTH

PROVISIONAL LICENSE FOR TISSUE BANK OPERATION

Issued in accordance with and pursuant to section 4364 Public Health Law of New York State

Facility ID: 506

Tissue Bank Director:

Michael J. Bauer, M.D., FACP, CTBS

Medical Director:

Michael J. Bauer, M.D., FACP, CTBS

Owner: CooperSurgical, Inc.

California Cryobank, LLC 950 Massachusetts Avenue Cambridge, MA 02139

is hereby APPROVED as a Tissue Bank for the following categories of service:

Comprehensive Tissue Procurement Service

Tissue Processing Facility

Tissue Storage Facility

Semen from donors and client-depositors

Semen from donors and client-depositors

Oocytes and embryos from donors and client-depositors that are collected and processed by tissue banks licensed by the Department in the correct categories

Issued: April 19, 2023

Expires: May 1, 2025

Property of the New York State Department of Health. Valid only at the address shown. Must be conspicuously posted.

DOH-3908 (04/2001)