



Department of Health

ANDREW M. CUOMO
Governor

HOWARD A. ZUCKER, M.D., J.D.
Commissioner

SALLY DRESLIN, M.S., R.N.
Executive Deputy Commissioner

October 5, 2018

Rosalind Low
Lead Regulatory Affairs Coordinator
NuVasive, Incorporated
7475 Lusk Boulevard
San Diego, CA 92121

Re: TS098

Dear Ms. Low:

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

NuVasive, Incorporated
4670 East Shelby Drive
Memphis, TN 38118

The provisional license is effective until either November 1, 2020 or the issuance of a full license following an on-site survey of your tissue bank, which will be undertaken to assess compliance with regulations 10NYCRR, Part 52. The certificate, which has been amended to reflect the addition of amniotic membrane, replaces that issued January 27, 2017. The certificate must be posted conspicuously at the approved location.

Please note that approval is limited to storage and distribution of musculoskeletal tissue and amniotic membrane that are recovered and processed by tissue banks licensed by the Department in the requisite categories. Please notify the Department at such time that you enter into tissue storage agreements with tissue processors so that we may verify appropriate New York State licensure.

In accordance with the provisions of 10 NYCRR 52-3.7(d), the Department will require an annual summary of the activities of your tissue bank. Information to be reported may include the numbers of tissue units stored and distributed.

Report changes in direct or indirect ownership of the facility within thirty (30) days of the change. Report changes in director within five (5) days and keep the Department informed of any relocation of facilities.

Regulations applicable to tissue banks, including tissue storage facilities, are available from this office and via a link online at <https://www.wadsworth.org/regulatory/tissue-resources>. If you have any questions, please call (518) 485-5341, or e-mail to btraxess@health.ny.gov.

Sincerely,

Robert A. Jordan
Tissue Bank Consultant
Tissue Resources

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

Tissue Bank ID No.: TS098

Director:

Carol R. Bleakley, Ph.D.

Medical Director:

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

**NuVasive, Incorporated
4670 East Shelby Drive
Memphis, TN 38118**

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

Tissue Storage Facility

**Musculoskeletal tissue
Amniotic membrane**

Issued: October 5, 2018

Owner: NuVasive, Incorporated

Expires: November 1, 2020

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

DOH-3908 (04/2001)