



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: TS057

Dear Ms. Low:

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

NuVasive, Incorporated  
7475 Lusk Boulevard  
San Diego, CA 92121

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](mailto: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.: TS057*

Director:

Carol R. Bleakley, Ph.D.

Medical Director:

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

NuVasive, Incorporated

7475 Lusk Boulevard

San Diego, CA 92121

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

Tissue Storage Facility

Musculoskeletal tissue

Amniotic membrane

Owner: NuVasive, Inc.

Issued: October 5, 2018

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)