DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 20, 2016

Innovatex, Inc.
Stephen C. Chen, President
150 Buckskin Drive
Weston, MA 02403

Re: DEN140022
Tear Duct Occluder
Evaluation of Automatic Class III Designation – *De Novo* Request
Regulation Number: 21 CFR 886.5838
Regulation Name: Nasolacrimal Compression Device
Regulatory Classification: Class I
Product Code: PLX
Dated: June 27, 2014
Received: July 18, 2014

Dear Mr. Chen:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your *de novo* request for classification of the Nasolacrimal Compression Device, a prescription device under 21 CFR Part 801.109 that is indicated *to temporarily occlude the nasolacrimal ducts in adult patients to reduce outflow through the nasolacrimal ducts*. FDA concludes that this device should be classified into class I. This order, therefore, classifies the Tear Duct Occluder, and substantially equivalent devices of this generic type, into class I under the generic name, Nasolacrimal Compression Device.

FDA identifies this generic type of device as:

> **Nasolacrimal Compression Device.** A nasolacrimal compression device is a prescription device that is fitted to apply mechanical pressure to the nasal aspect of the orbital rim to reduce outflow through the nasolacrimal ducts.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This new law provides two options for *de novo* classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may, within 30 days of receiving notice of the NSE determination, request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the

initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** classifying the device type.

On July 18, 2014, FDA received your *de novo* requesting classification of the Tear Duct Occluder into class I. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Tear Duct Occluder into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

After review of the information submitted in the *de novo* request FDA has determined that the Tear Duct Occluder, indicated *to temporarily occlude the nasolacrimal ducts in adult patients to reduce outflow through the nasolacrimal ducts*, can be classified in class I. FDA believes that class I (general) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks to health are improper fit of the device (extended or aggressive use of this device may cause sequelae such as bruising and/or soreness) and improper use of the device (for the uncoordinated, a corneal abrasion may occur inadvertently).

The Nasolacrimal Compression Device is subject to the general controls of the FD&C Act. Section 510(l) of the FD&C Act (21 U.S.C. 360(l)) provides that a class I device is not subject to the premarket notification requirements under section 510(k) of the FD&C Act unless the device is of substantial importance in preventing impairment of human health or presents a potential unreasonable risk of illness or injury. FDA has determined that the device does meet these criteria and, therefore, premarket notification is not required for the device. Thus, persons who intend to market this device need not submit a premarket notification containing information on the Nasolacrimal Compression Device they intend to market prior to marketing the device subject to the limitations on exemptions in 21 CFR 886.9.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Please be advised that FDA's decision to grant this *de novo* request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD & C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the **Federal Register**. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the *de novo* request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact Daniel P. Fedorko, Ph.D., at 301-796-6620.

Sincerely,

Jonette R. Foy -S

Jonette Foy, Ph.D.
Deputy Director
for Engineering and Science Review
Office of Device Evaluation
Center for Devices and
Radiological Health