Catalina, Inc.
c/o Discovery Group, LLC
Richard J. Freer, Ph.D.
8110 Westbury Drive
Richmond, Virginia 23229

July 28, 2023

Re: K102742
Trade/Device Name: NasalCEASE®
Regulatory Class: Unclassified
Product Code: QSY

Dear Richard J. Freer, Ph.D.:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated February 2, 2011. Specifically, FDA is updating this SE Letter because FDA has better categorized your device technology under product code QSY.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Julie Morabito, OHT4: Office of Surgical and Infection Control Devices, 240-402-3839, Julie.Morabito@fda.hhs.gov.

Sincerely,

Julie A. Morabito -S

Julie Morabito, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Catalina, Inc.
% Discovery Group, LLC
Richard J. Freer, PhD
8110 Westbury Drive
Richmond, Virginia 23229

FEB - 2 2011

Re: K102742
Trade/Device Name: NasalCEASE®
Regulatory Class: Unclassified
Product Code: FRO, EMX
Dated: January 6, 2011
Received: January 7, 2011

Dear Dr. Freer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the 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 Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

K102742

Device Name: NasalCEASE®

Indications for Use:

This device has the following intended use.

NasalCEASE® is intended to be used as a topical dressing for the local management of bleeding wounds such as minor cuts, lacerations, and abrasions. NasalCease® is already approved for treatment of minor nosebleeds.

It is intended to be marketed and sold as an Over-The-Counter device.

The device is not intended to be used for medium or severe wounds or bleeding.

LEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use __X____
(Per 21 CFR 801.109)

David Krause for MLM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102742

K102742

510(k) Summary

FEB - 2 2011

Submitter: Catalina, Inc.
3870 Rush Mendon Road
Mendon, New York 14506.
Phone: 585-624-7540
Fax: 585-624-9678
Contact Mr. Bruce M. Ford, President

Name: Regulation Name: Dressing, wound, drug
Regulatory Class: Unclassified
Product Code: FRO
Trade Name: NasalCEASE®

Substantially Equivalent to: BleedArrest® (K070211); NasalCEASE® (K041446)

Description of the device: NasalCEASE® is comprised of calcium alginate and is manufactured as a sheet (2x4x0.5 cm) of interwoven threads or as particles.

Intended Use: NasalCEASE® is intended to be used as a topical dressing for the local management of bleeding wounds such as minor cuts, lacerations, and abrasions. NasalCease® is already approved for treatment of minor nosebleeds (K041446).

It is intended to be marketed and sold as an Over-The-Counter device.

The device is not intended to be used for medium or severe wounds or bleeding.

Technological Characteristics: NasalCEASE® is comprised of calcium alginate that can be applied topically. Upon contact with blood or other physiological fluids it adsorbs those fluids and swells to apply a compressive force. BleedArrest® is used in the same way but acts by adsorbing fluid and causing hemoconcentration at the wound site which accelerates coagulation.

Performance Testing: The products have been extensively tested and found to be biocompatible. They have been the test article used to support several previous 510(k) products (K905314, K922540, and K984069) used for medical/surgical applications.

No performance standards have been established under Section 514 of the Food, Drug, and Cosmetic Act for this device.

Summary: The NasalCEASE® device described in this submission is substantially equivalent to the predicate devices, is safe and effective, and sufficiently simplified and explained to be sold as an OTC product.