DE NOVO CLASSIFICATION REQUEST FOR NASOLACRIMAL COMPRESSION DEVICE

REGULATORY INFORMATION

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.

NEW REGULATION NUMBER: 886.5838

CLASSIFICATION: Class I (**Exempt** from premarket notification review, subject to the limitations in 21 CFR 886.9)

PRODUCT CODE: PLX

BACKGROUND

DEVICE NAME: NASOLACRIMAL COMPRESSION DEVICE

SUBMISSION NUMBER: DEN140022

DATE OF DE NOVO: JULY 18, 2014

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REQUESTER'S RECOMMENDED CLASSIFICATION: CLASS I

INDICATIONS FOR USE

Nasolacrimal Compression Device (NCD) is indicated to temporarily occlude the nasolacrimal ducts in adult patients to reduce outflow through the nasolacrimal ducts.

LIMITATIONS

The Nasolacrimal Compression Device is for prescription use only.

Select Warnings and Precautions

- Serious injury may result if the device is used in cases of open globe, post-surgery, infection, and inflammation.

- This device has not been evaluated for pediatric use.

- Do not use this device if you are on anti-coagulants as use of this device may cause bruising.

PLEASE REFER TO THE LABELING FOR A MORE COMPLETE LIST OF WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS.

RATIONALE FOR EXEMPTION

The technology of a non-invasive, nasolacrimal compression device is limited to mechanical-based pressure. Thus, the risks associated with use of the device are low. Therefore, a non-invasive compression device for the nasolacrimal ducts, when indicated for prescription use, is appropriate for exemption from premarket notification and is also subject to the limitations of exemptions identified in 21 CFR 886.9. Given the simplicity of the design, including the lack of any electrical components, general controls provide reasonable assurance of safety and effectiveness if device manufacturers comply with such requirements, which includes current good manufacturing practice requirements (21 CFR part 820), and general labeling (21 CFR part 801).

An example of exceeding the limitations of the class I exemption could include a significant change in the technological characteristics used to apply pressure to the nasolacrimal ducts (e.g., electronically controlled pressure).

Indications for increased adsorption or effectiveness of eye drop medications or efficacy for specific diseases or indications would exceed the scope of the regulation and would require submission of a new de novo application with data to support the new intended use.

DEVICE DESCRIPTION

The Nasolacrimal Compression Device is a modified spectacle frame made of polyvinyl chloride (PVC) coated soft carbon steel wire covered with silicone rubber where the device contacts the nose bridge (See Figure 1 below). The fastening bands are made from flame-retardant nylon hook and loop fabric. The following differences exist between the subject device and a "normal" spectacle frame:

- The frame width, nose bridge width, and nose pad shape of the subject device may be adjusted.

- The nose pad is contoured such that it lies over the nasal aspect of the orbital rims where the nasolacrimal systems are underneath.

- There are fastening bands attached to each temple that allow the user to adjust pressure applied to the nasolacrimal system.

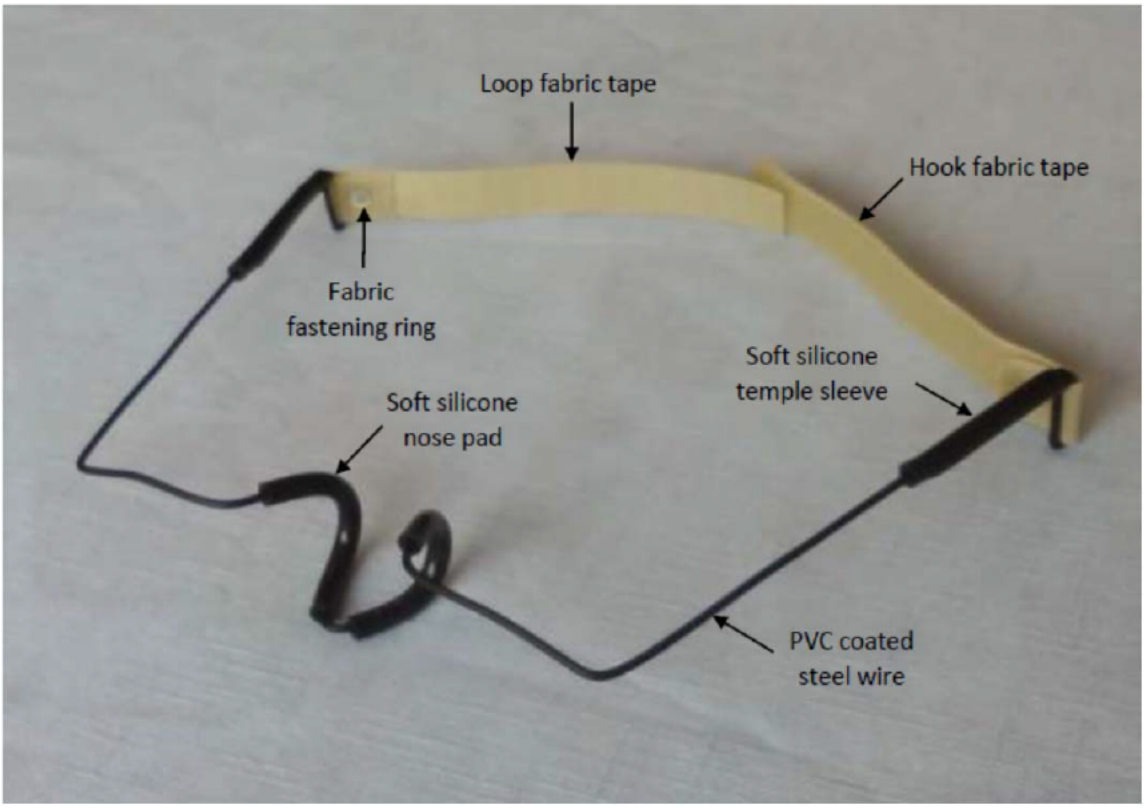

Figure 1. Components of the Nasolacrimal Compression Device (used by permission).

Principle of Operation and Design Goals

Occlusion of the nasolacrimal system may reduce drainage through the ducts, allowing fluid to remain on the surface of the eye for a longer period of time. One such application of the device could be with the administration of eye drops, as the current standard-of-care is to manually occlude the nasolacrimal ducts by pressing on the nasal aspect of the orbital rim with a finger for 5 minutes after adding eye drops. The Nasolacrimal Compression Device is designed to substitute for this manual occlusion of the nasolacrimal ducts.

SUMMARY OF NONCLINICAL/BENCH STUDIES

Bench testing included a leak test, spring test, pressure testing, and device endurance testing, which are summarized in Table 1 below:

Table 1. Summary of Bench Testing for the NCD.

Test Performed	Expected Outcome	Test Details	Conclusions
Spring Test	No deformation of the spring under normal use, when the imposed force is smaller than the yield force of the spring.	1. The temple is fixed and the force is applied at the center of the nose pads. As the weight reached W1, the device frame will begin to deform and will not	Fyield (W1): b(4)

Test Performed	Expected Outcome	Test Details	Conclusions
		return to its original shape when the weight is removed. 2. The W2 (force at center of nose pads) is defined as the person feels that both nose pads begin to separate from the skin.	Fnormal (W2): b(4) CCI
Pressure Tests	1. Pressure applied on the nasolacrimal ducts under the normal use is ≤ the pressure exerted by a standard eyeware 2. No discomfort	See details of calculation below.	Pnormal: b(4) CCI below safety limit from the literature
Metal Fatigue Test of NCD	NCD frame can sustain repeated twisting spring motions during normal use.	Alternate 1000 times between yield weight, W1, with the normal use weight, W2.	The nose pad section can sustain repeated twisting spring motions 1,000 times during normal use. None of the tested devices broke at the end of the test. For multiple eyedrop users, who administer eyedrops 3 times a day, this amount of usage would cover half of a year of device use.
Hook and Loop Bands Test	Determine the number of attaching/detaching operations for hook and loop bands without compromising their gripping capability.	The hook and loop bands are manually attached with 1 inch overlap and then detached from each other.	The hook and loop bands can maintain their gripping capability for 600 times of repeated use.

Pressure Tests

Objective and Pass/fail Criteria

The maximum pressure the NCD can apply to the nasolacrimal ducts was determined. The pressure applied on the nasolacrimal ducts under normal use conditions should be below 6 psi (the skin tolerable pressure under bony prominences as supported by literature articles provided by the applicant).

Test Method

The maximum pressure applied on the nasolacrimal ducts was evaluated analytically using a 3D model of the NCD. For their analysis, the applicant used yield and separation force values obtained in the spring test. In their analysis of pressure distribution along the nose pad they determined that the nose pad skin contact length is between b(4) CCI and the outer diameter of the silicone rubber tube b(4) CCI The results showed that the maximum pressure point is at center of the nose pad (where it directly overlays the nasolacrimal ducts) is below b(4) CCI. The analysis also showed that the yield pressure (i.e., the maximal pressure for deformation of the device) does not exceed 3.9 psi.

Pressure Test Conclusion

With regard to the comfort level of wearing NCD under the normal use condition, the normal pressure applied on the nasolacrimal systems by wearing NCD is about 1.6 psi. The risk of excessive pressure is mitigated by design limitations of a yield pressure of 3.9 psi. This amount of yield pressure should not cause adverse effects.

BIOCOMPATIBILITY/MATERIALS

The primary patient contacting material is silicone rubber tubing. The PVC coated carbon steel wire used to construct the device frame and the nylon hook and loop fabric fastener straps may also contact intact skin. The materials used to construct the NCD were not manufactured or modified by the device manufacturer. Since the materials are widely used for medical devices and the duration of contact is for less than 24 hours, biocompatibility testing was not needed for this device.

SHELF LIFE/STERILITY

The NCD is not intended for use in any sterile application. It is not to be used by any individual who is maintaining, entering, or contacting any sterile field. In addition, this device is intended to be used by a single patient. The labeling recommends weekly cleaning with an alcohol wipe or moistened facial tissue.

SUMMARY OF CLINICAL INFORMATION

Demonstration of Clinical Effectiveness

Clinical evaluations were performed on a single subject to demonstrate the effectiveness of the device to occlude the nasolacrimal ducts. This is acceptable to demonstrate reasonable assurance of safety and effectiveness for the limited use of for the tool claim for the NCD. However, any claims of clinical effectiveness for a nasolacrimal compression device would require extensive clinical data.

Dye Disappearance Test

Performance of the simplified dye disappearance test by an eye care professional is the most effective means to ensure proper fit. The simplified dye disappearance test used a moistened fluorescein strip to instill fluorescein into the conjunctival fornices of each eye and the tear film was observed using the cobalt blue filter of a slit lamp. This test was performed on one subject and it revealed that NCD was able to occlude nasolacrimal drainage.

Clinical Study

Two eyes were tested on one subject with this simplified dye disappearance test by a board-certified ophthalmologist to verify temporary nasolacrimal duct occlusion. The outcome was that persistence of dye was achieved bilaterally for 5 minutes. No adverse events were reported.

Fitness Adjustment Validation

Seven subjects of different ethnicity and age were recruited to determine how well patients could follow verbal and written instructions for fitting the device to the proper position on the face. The subjects performed the fitness adjustments with assistance. A simplified dye disappearance was performed on one subject to demonstrate that nasolacrimal drainage was obstructed. The trial group for fitness testing consisted of 2 Asian females, 2 Asian males, 2 white females, and one white male.

The conclusions from the fitness adjustment validation were that patients could fit the device to their face following instructions as would be provided by a clinician. No adverse events were reported in this study.

LABELING

The Nasolacrimal Compression Device is a prescription-use device intended for home use. The labeling for the Nasolacrimal Compression Device consists of the User Guide. In addition to the precautions, warnings, and contraindications mentioned above, the guide provides fitting instructions for the user and the clinician with a description of the dye disappearance test to be used by a clinician when fitting the device to the patient. Other information provided to the user includes pressure adjustments, maintenance, storage, and use life for the device.

RISKS TO HEALTH

The risks to health that may be associated with use of the Nasolacrimal Compression Device 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.

General controls are sufficient to mitigate these risks.

BENEFIT/RISK DETERMINATION

The risks of the device are based on data collected in a clinical study and a fitness adjustment validation study described above. No adverse events were reported in the fitness adjustment validation study (7 participants) or in the clinical use study involving a single subject who used

the device for 3 years. Possible complications from use of the Nasolacrimal Compression Device include:

- Particularly in the elderly on anticoagulants, prolonged and/or "too tight" use of this device (i.e., 5 hours instead of 5 minutes) may cause sequelae such as bruising.

The probable benefits of the device are also based on data collected in a clinical study as described above. Limited effectiveness has been demonstrated because it appears that only a single subject was tested with a simplified dye disappearance. While we do believe there is probable benefit with this device, it is unclear whether the test device may be used in a wide-scale by other patients and physicians with similar results due to the limited data and experience with this device.

In conclusion, given the available information, the sponsor has demonstrated that the device has utility to occlude the nasolacrimal duct in adults. Based on known information about the device, the probable benefits outweigh the probable risks for the Nasolacrimal Compression Device. Furthermore, the risks can be adequately mitigated by the use of general controls alone, which includes labeling requirements (i.e., 21 CFR 801) in accordance with a Class I device.

CONCLUSION

The *de novo* for the Nasolacrimal Compression Device is granted and the device is classified under the following:

Product Code: PLX
Device Type: Nasolacrimal Compression Device
Class: I (Exempt from premarket notification, subject to the limitations in 21 CFR 886.9)
Regulation: 886.5838