DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 1, 2015

Dynarex Corporation
Mr. James Hurlman
Manager, Regulatory Affairs
10 Glenshaw Street
Orangeburg, NY 10962

Re: K151575
Trade/Device Name: Dynarex Eye Cups
Regulation Number: None
Regulation Name: Eye Cup
Regulatory Class: Unclassified
Product Code: LXQ
Dated: May 30, 2015
Received: June 29, 2015

Dear Mr. Hurlman:

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 801and Part 809); 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 and Part 809), please contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Kesia Y. Alexander -A

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151575

Device Name
Dynarex Eye Cup

Indications for Use *(Describe)*
The Dynarex Eye Cup is a non-sterile device made of opaque Polyethylene designed to be filled with an eyewash solution and placed over the eye to allow the solution to wash out or flush the affected eye.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) SUMMARY

THIS SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION IS BEING SUBMITTED IN ACCORDANCE WITH THE REQUIREMENTS OF THE SAFE MEDICAL DEVICES ACT OF 1990.

Assigned 510(k) number is: K151575

Submitter	Dynarex Corporation 10 Glenshaw Street Orangeburg, NY 10962 USA Phone: 845-365-8200 Fax: 845-680-6717
Contact Person	James Hurlman
Date of Summary	05/30/2015
Trade Name	Dynarex Eye Cup**,** Model 3380
Device Classification Name	Cup, Eye
Common Name	Eye cup
Classification	Opththalmic – Unclassified – Pre-Amendment
Product Code	LXQ
Predicate Device	Flents Plastic Eye Wash Cup 510(k) #: K140409
Device Description	The Dynarex Eye Cup is a 12ml plastic cup, manufactured with polyethylene plastic that is designed to be filled with an eye wash solution and placed over the eye to allow the solution to wash out or flush the affected eye. The cup is non-sterile and is re-usable.
Comparison to Predicate Device	The Dynarex Eye Cup has the same intended use and similar design as the predicate device and is substantially equivalent with regards to safety and effectiveness.

510(K) SUMMARY

K151575

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Intended Use

The Dynarex Eye Cup is a non-sterile device made of opaque Polyethylene designed to be filled with an eyewash solution and placed over the eye to allow the solution to wash out or flush the affected eye.

Differences:

The design differences include the products material where our device is made of LDPE and the predicate device is made of ABS plastic. The color of the predicate device is white due to an added colorant and the Dynarex version is naturally whitish and/or opaque with no colorant added. The predicate device has a 2mL greater fluid capacity. Both devices are sold non-sterile and are reusable. Neither Dynarex nor the predicate device have established a patient population for the use of the product, in an emergency situation the product can be used effectively, with care, on any age.

Table of Comparison

Characteristic	Applicant Device Dynarex CPR Shield	Predicate Device Flents Plastic Eye Wash Cup
Classification Name	Cup, Eye	Cup, Eye
Intended Use	The Dynarex Eye Cup is a non-sterile device is placed over the eye to allow the solution to wash out or flush the affected eye.	The Flents Eye Wash Cup is intended to hold liquids such as eye wash solution, used to flush out the eye.
Design	Polyethylene	ABS Plastic
Color	Natural molded color – no colorant - whitish/opaque	TZE Kun Plastic Materials. No. 216941 White
Volume	17ml	0.65 fl. Oz. (19ml)
Dimensions	1.732 in x 1.062 in	1.903 in x 1.353 in
Materials	Sinopec Yangzi Pertrochemical Co. Ltd. LDPE – No. 2426H	Chi Mei ABS No. PA-757
Sterility	Non Sterile	Non Sterile
Reuse	Reusable	Reusable
Labeling / Cleaning Instructions	"Wash cup thoroughly with soap and warm water before use. Rinse well and dry to ensure eye wash cup is not contaminated with any previous liquids or materials prior to each use"	"Wash cup thoroughly with soap and warm water before use. Rinse well and dry to ensure eye wash cup is not contaminated with any previous liquids or materials prior to each use"

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510(K) SUMMARY

Summary of Safety and Effectiveness of Applicant Device

Biocompatibility testing of the applicant material includes Acute Systemic Toxicity, In-Vitro Cytotoxicity, Occular Irritation and Maximization Sensitization. Results of the biocompatibility testing showed no evidence of cellular or systemic toxicity, ocular irritation, or a sensitization response. All materials used in the manufacture of the Dynarex Eye Wash Cup have demonstrated to be substantially equivalent in regards to safety and effectiveness to the predicate device and are safe for its intended use.

Conclusion

The Dynarex Eye Wash Cup is substantially equivalent to the predicate device with regards to intended use, design and substantially equivalent as it relates to safety and effectiveness to the predicate device via biocompatibility testing.