Apothecary Products, Inc.®

JUL 09 2014

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92 (c)

The assigned 510(k) number is: K140409

Applicant:	Apothecary Products, Inc. 11750 12th Avenue South Burnsville, MN 55337 FDA Establishment Registration Number: 2183416
Contact person:	James Jenkins Sr. Regulatory Affairs Specialist Phone: 952.808.8364 Fax: 952.890.0418
Date prepared:	June 12, 2014
Name of Device:	Flents Plastic Eye Wash Cup
Device Classification Name:	Cup, Eye
Common or usual name:	Eye Cup
Classification:	Ophthalmic - Unclassified – Pre-Amendment
Product Code:	LXQ
Predicate Device information:	K051414
Device Description:	The Flents Plastic Eye Wash Cup is a 0.65 fl. oz. (19 mL) plastic cup manufactured with Chi- Mei ABS PA-757 White plastic that is 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. The Flents Plastic Eye Wash Cup is non-sterile and is re-usable.

Intended Use: The Flents Plastic Eye Wash Cup is intended to hold liquids such as eye wash solutions, used to flush out the eye.

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Comparison to Predicate Device:

The Flents Plastic Eye Wash Cup has the same intended use and a similar design as the predicate device and is substantially equivalent with regards to safety and effectiveness.

Discussion of Non-Clinical Tests Performed in Determination of Substantial Equivalence:

Biocompatibility testing performed by third party laboratories demonstrated the material is safe for use in contact with solutions used to wash the affected eye.

Comparison to Predicate Device

Attribute	Applicant Device; Flents Plastic Eye Wash Cup	Predicate Device; Tollot Pty.Ltd.(Aaxis Pacific), Non-sterile K051414
Classification Name	Cup, Eye	Cup, Eye
Intended Use	The Flents Plastic Eye Wash Cup is intended to hold liquids such as eye wash solutions, used to flush out the eye.	A cup that holds liquids, such as eye wash solution, used to flush out the eye.
Design	ABS Plastic receptacle for eyewash solutions.	Similar
Colors	TZE Kun Plastic Materials, No. 216941 White	Unknown
Dimensions	1.903 in x 1.353 in	Similar from redacted drawings
Volume	0.65 fl. oz. (19 mL)	Unknown
Materials	Chi Mei ABS PA-757	Unknown
Sterile	Non-sterile	Sterile/Non-sterile
Reuse	Reusable	Sterile Cup not reusable

Differences:

The Flents Plastic Eye Wash Cup is a non-sterile reusable device. The predicate device includes a sterile and non-sterile configuration that may not be reusable. The Flents Plastic Eye Wash Cup provides instructions to "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. The Flents Plastic Eye Wash Cup is not packaged as sterile, however if cleaned as directed prior to each use, the eye cup is safe and effective "to hold liquids such as eye wash solutions used to flush out the eye" for its intended use, and is substantially equivalent with

regards to safety and effectiveness as the predicate device based on our eye cup material biocompatibility testing.

Summary of Safety and Effectiveness of Applicant Device

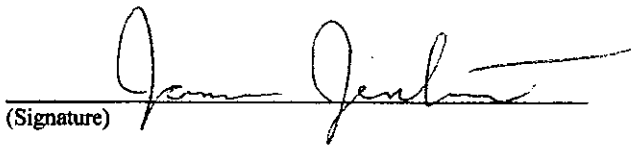
Biocompatibility testing of the applicant material and colorant included Acute Systemic Toxicity, In-vitro Cytotoxicity, Ocular Irritation and Maximization Sensitization. Studies were performed to assess the biocompatibility of the Flents Plastic Eye Wash Cup. Results of the biocompatibility testing show no evidence of cellular or systemic toxicity, ocular irritation, or a sensitization response. All materials used in the manufacture of the Flents Plastic Eye Wash Cup have demonstrated to be substantially equivalent with regards to safety and effectiveness, to their predicate devices and safe for its intended use.

Conclusion:

The Flents Plastic Eye Wash Cup is substantially equivalent to the predicate device in regards to intended use, design, and substantially equivalent with regards to safety and effectiveness. All the materials used in the Flents Plastic Eye Wash Cup have passed the relevant biocompatibility tests and have demonstrated to be safe and effective for the applicant intended use.

Truthful and Accuracy Statement

Truth and Accuracy Statement
I certify that, in my capacity as Senior Regulatory Specialist of Apothecary Products Inc., I believe to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate, and no material fact has been omitted (as required by 21 CFR 807.87(k)).



(Signature)

James Jenkins

February 12, 2014

(Premarket Notification [510(k)] Number)

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

July 9, 2014

Apothecary Products, Inc.
Mr. James Jenkins
Senior Regulatory Specialist
11750 12th Avenue South
Burnsville, MN 55337-1295

Re: K140409
Trade/Device Name: Flents Plastic Eye Wash Cup
Regulation Number: None
Regulation Name: Eye Cup
Regulatory Class: Unclassified
Product Code: LXQ
Dated: 06/12/2014
Received: 06/19/2014

Dear Mr. Jenkins:

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 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" (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 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 -S

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

Apothecary Products, Inc.®
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Indications for Use

510(k) Number (if known): K140409

Device Name: Plastic Eye Wash Cup

Indications for Use:

The Apothecary Products, Inc. Plastic Eye Wash Cup is intended to hold liquids such as eye wash solutions, used to flush out the eye.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Naima B. Jacobs-el -S
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