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510(k) Summary

DATE SUMMARY REVISED: November 27, 1996

SUBMITTER:

Submitted on behalf of:

The CLENSER Corporation
Address: 7100 Boyd Avenue
Eden Prairie, MN 55346-3534
Telephone: 612-934-1616

by:

Paladin Medical, Inc.
P. O. Box 560
Stillwater, MN 55082

CONTACT PERSON: Elaine Duncan

TRADE NAME: ACU-CLENS™ Cleaning Accessory
COMMON NAME: Contact Lens Cleaning Accessory

SUBSTANTIALLY EQUIVALENT TO: The CLEANER™ Accessory by Easy Eyes, Eaton Medical Corporation

DESCRIPTION: ACU-CLENS™ Cleaning Accessory for Contact Lens Cleaning is a method of cleaning contact lenses that mimics the figure-eight hand-in-palm motion. The ACU-CLENS™ Cleaning Accessory can be used with hard (gas permeable) and soft (hydrophilic) lenses. ACU-CLENS™ Cleaning Accessory features a durable plastic case and disposable foam pads for use with professionally recommended daily cleaning solutions. The hinge mounted base and cover contain right and left lens receptacles and four mounting posts which secures the disposable pad to the base. The cover provides a motion plate, cleaning head domes and a hinged latch to secure the disposable pad to the cleaning head domes. Daily cleaning solution (recommended by an eye care professional or physician) is applied to the disposable pad secured to the cleaning head domes and the right and left receptacle and the lenses are placed on the disposable pad above the right and left receptacle. After closing the case the motion plate on the cover is moved in a figure-8 motion to create the scrubbing effect necessary to clean both top and bottom of each lens simultaneously. Lenses should be thoroughly disinfected using solution recommended by physicians or eye-care professionals. The disposable pad should be removed and discarded and the Cleaning Case disinfected after each use.

INDICATIONS FOR USE: ACU-CLENS™ Cleaning Accessory is indicated for use with recommended contact lens cleaning solutions for cleaning soft (hydrophilic) and rigid gas permeable contact lenses in accordance with directions for use in the solution labeling. The device aids in cleaning by minimizing hand contact with lenses.

SUPPORTING INFORMATION: The ACU-CLENS™ Cleaning Accessory is intended for use with a fresh pad each use, whereas THE CLEANER ACCESSORY™ by Easy Eyes® recommends cleaning and reuse of the pads. The CLENSER Corporation does not recommend reuse of the cleaning pads. Labeling instructions for use of the ACU-CLENS™ Cleaning Accessory state that the cleaning pads should not be reused. Replacement pads are available, sold separately. The foam pads used in the ACU-CLENS™ Cleaning Accessory have been tested for cytotoxicity and eye irritation and have been found to be non-toxic and non-irritating. The ACU-CLENS™ Cleaning Accessory has been designed to minimize the hand contact with lenses normally associated with cleaning instructions accompanying cleaning solutions. The CLENSER Corporation has tested lenses with the ACU-CLENS™ Cleaning Accessory, the results of which are represented by Scanning Electron Microscope photographs.