

DEC 17 1996

K964289

510(k) Summary

SUBMITTER:

Submitted on behalf of:

Company Name: **eyeFix™, Inc.**
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DATE SUMMARY PREPARED: October 25, 1996

TRADE NAME: eyeFix™, Inc. Eye Fixation Speculum

COMMON NAME: ophthalmic speculum

SUBSTANTIALLY EQUIVALENT TO: The Eye Fixation Speculum, by eyeFix™, Inc. is substantially equivalent to two products currently legally marketed in the U.S. The Eye Fixation Speculum is substantially equivalent to the **indication for use** of the Lid-Set Eyelid Retractor manufactured by Universi, S.A. This device was determined by FDA to be exempt from 510(k) notification per K903322. The Eye Fixation Speculum is substantially equivalent to the **stabilization method** (technology) used in numerous manual ophthalmic instruments such as the Hessburg-Barron Vacuum Trephine as manufactured by Precision Instruments, Inc. This device was cleared by FDA in K864520. Additional products in the same family line were cleared under K843048 and K923540.

DESCRIPTION of the DEVICE: The Eye Fixation Speculum, by eyeFix, Inc., consists of a low profile scleral vacuum ring attached to a medical quality plastic ophthalmic speculum using a six-degrees of freedom resistance joint. After retracting the eyelids, and securing the speculum, the vacuum ring is attached to the sclera by locating the medical quality concentric elastomer-ring to the cornea. Vacuum is applied

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by way of the attached spring-loaded syringe. When vacuum is applied, the flexible elastomer portion of the ring sucks down on the scleral region of the eye securing the ring to the eye. The frictional forces within the resistance joint of the attaching arm of the speculum, together with the vacuum ring, hold the eye steady against the tendency of the eye muscles to move the globe. Although this resistance is high enough to prevent the eye from moving, the force is not so high that the physician is prevented from conveniently moving the ring within the range of motion that the joint allows. Luminescent plastic on the upper portion of the ring helps in visualization of the eye under low examination lighting.

INDICATIONS FOR USE: The Eye Fixation Speculum, by eyeFix™, Inc. is intended to reduce eye movement and stabilize the eye in any procedure in which the globe needs to be immobilized. The device is provided sterile and is disposable for single use only.

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