K971245

JUN 20 1997 CONFIDENTIAL DOCUMENT

8. 510(k) Summary of Safety and Effectiveness

In accordance with CFR 807.92 (April 26, 1992), the following information is submitted:

1. Name: Ipax, Inc.
   Address: 2109 West Amherst
   Englewood, CO 80110

   Telephone: 303-781-2444
   Fax 303-781-2505

   Contact: Phillip Pennell

   Date of Summary Preparation: March 30, 1997

2. Name of Device: Blink™ External Eyelid Weights
   Common Name: External Eyelid Weights
   Classification Name: None known

3. Predicate Device: Gold Eyelid Implants, EyeClose External Eyelid Weights, preamendment and equivalent devices, respectively.

4. Device Description:
   The Blink External Eyelid Weights are spherically radiused strips of pure tantalum, constructed in twelve sizes ranging from 0.6 grams to 2.8 grams in 0.2 gram increments.

   The Blink External Weight is attached to the outer skin of the upper eyelid with a double coated adhesive tape strip or with mastisol.

   Blink External Eyelid Weights are offered in four flesh tone colors:
   White, Tan, Medium Brown and Dark Brown

   Only the top surface of the weight is painted. The underneath surface is bare tantalum metal.

   The physical specifications and materials used in the construction of the Blink External Eyelid Weights are identical to the EyeClose External Eyelid Weights.

5. Intended Use:
   Blink External Eyelid Weights, attached to the outer skin of the upper eyelid with an adhesive, work by gravity to restore a functional blink mechanism to the patient who suffers from lagophthalmos resulting from temporary or permanent facial paralysis, specifically the orbicularis oculi muscle. This paralysis may be the result of Bell's palsy or from surgical trauma to the facial nerve.

Functional defects which may be corrected or avoided with the use of Blink External Eyelid Weights include inadequate eyelid closure, corneal exposure, serious keratopathy such as ocular irritation, keratitis, corneal abrasion or ulceration. These conditions may result in decreased vision.

6. Technological Characteristics of the Device:
Blink External Eyelid Weights are produced to the same specifications as the EyeClose External Weights.

Blink External Eyelid Weights are constructed of pure tantalum. The weights are designed in a rectangular shape with a spherical radius of curvature of 12.7 mm which conforms to the shape of the eye. All edges are smoothly rounded.

The top surface is painted with a Polane 2.8 T Plus polyurethane enamel paint. The material safety data sheet is enclosed in appendix 4.

SUBSTANTIAL EQUIVALENCE COMPARISON

	Blink External Eyelid Weight (Ipax)	Series 1000 External Eyelid Weight (MedDev)
Indications for Use	Same	Same
Target Population	Same	Same
Design	Same	Same
Materials	Same	Same
Performance	Same	Same
Sterility	Same	Same
Biocompatibility	Same	Same
Mechanical Safety	Same	Same
Anatomical Site	Same	Same
Human Factors	Same	Same
Where Used	Same	Same

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 20 1997

Mr. Phil Pennell
IPAX, Inc.
2109 West Amherst Ave.
Englewood, CO 80110

Re: K971245
Trade Name: Blink™ External Eyelid Weight
Regulatory Class: I
Product Code: 86 MML
Dated: March 30, 1997
Received: April 3, 1997

Dear Mr. Pennell:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

Blink External Eyelid Weight are attached with an adhesive tape or gum to the outer surface of the upper eyelid. This weight acts by gravity to restore a functional blink mechanism to the patient who is afflicted with lagophthalmos. Usually the adhesive is changed daily after bathing.

The patient with lagophthalmos is unable to close the eyelid completely because of partial or complete paralysis to the facial nerve. This paralysis may be the result of Bell's palsy or from surgical trauma to the facial nerve. The condition of paralysis can be either permanent or transient.

Susan Gouge KVA for DRL
(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K971245

Prescription Use Susan Gouge
(Per 21 CFR 801.109)