

R 771242

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 80150

DEC 17 1997

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

Contact: Phillip Pennell

Date of Summary Preparation: February 28, 1997

- 2. Name of Device: Blink™ Gold Eyelid Weight Implants
Common Name: Gold Eyelid Weights
Classification Name: None known

- 3. Predicate Device: Series 3000 Gold Eyelid Implants, a preamendment device

- 4. Device Description:
The Blink Gold Eyelid Weight Implants are spherically radiused strips of pure gold, constructed in twelve sizes ranging from 0.6 grams to 2.8 grams in 0.2 gram increments. All product specifications are identical to the predicate device, the Series 3000 Gold Eyelid Implant, produced by MedDev Corporation.

The Blink Gold Eyelid Weight Implant is implanted into the eyelid following the surgical technique described in the product brochure. This technique is identical to the technique used to implant the predicate device, the Series 3000 Gold Eyelid Implant.

- 5. Intended Use:
Blink Gold Eyelid Weight Implants, surgically implanted in the upper eyelid, work by gravity to restore a functional blink mechanism in the patient with 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 Gold Eyelid Weight Implants include inadequate eyelid closure, corneal exposure, serious keratopathy such as ocular irritation, keratitis, corneal abrasion or ulceration. These conditions may result in decreased vision.

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The intended use of the Blink Gold Eyelid Weight Implant is identical to the intended use of the predicate device, the Series 3000 Gold Eyelid Implant.

6. **Technological Characteristics of the Device:**
Blink Gold Eyelid Weight Implants are constructed of pure gold (99.99%). 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. Suture holes are placed in the implant to allow the surgeon to secure it to the tarsus or orbital septum.

In the engineering specifications, dimensions are stated in the plano view. In the product literature, dimensions are stated in the radiused view.

All technological characteristics of the Blink Gold Eyelid Weight Implants are identical to the technological characteristics of the predicate device, the Series 3000 Gold Eyelid Implant.

SUBSTANTIAL EQUIVALENCE COMPARISON

	Blink Gold Eyelid Implant (Ipax)	Series 3000 Gold Eyelid Implant (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



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 17 1997

Mr. Phillip E. Pennell
President, CEO
IPAX, INC.
2109 W. Amherst
Englewood, CO 80110

Re: K971242
Trade Name: Blink Gold Eyelid Weight Implants
Regulatory Class: Pre-amendment unclassified
Product Code: 86 MML
Dated: November 25, 1997
Received: December 1, 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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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

