510(k) SUMMARY

NAME OF FIRM:	Argus Biomedical Pty Ltd
510(k) CONTACT PERSON:	Barbara S. Fant, Pharm.D. Consultant
TRADE NAMES:	AlphaCOR™, AlphaCor-A™, AlphaCor-P™
COMMON NAME:	Artificial Cornea
CLASSIFICATION:	886.3400(II) Keratoprosthesis, permanent implant
PRODUCT CODE:	HQM
SUBSTANTIALLY EQUIVALENT DEVICE:	Dohlman Doane Type I Keratoprosthesis

INTENDED USE:
The AlphaCor artificial cornea is intended for use as a keratoprosthesis in adult patients with corneal opacity to include the following:

- Eyes that are not suitable for standard penetrating keratoplasty with donor tissue.
- Eyes in patients who have declined to have standard penetrating keratoplasty performed with donor tissue.
- Eyes in which the adjunctive measures required to prevent graft rejection are medically contraindicated.

DEVICE DESCRIPTION:
The AlphaCor artificial cornea is made of flexible hydrogel PHEMA and comprises an optically clear core surrounded by a peripheral opaque sponge rim, which allows tissue ingrowth. The core allows transmission of light and provides refractive power, while the sponge skirt allows fibrovascular ingrowht for long term securing of the device into place. The AlphaCor device is implanted in a two stage surgical process using a modified intrastromal lamellar technique that places the posterior surface of the optic in direct communication with the anterior chamber, covers the anterior surface of the optic with the anterior corneal lamella and, usually, a conjunctival flap, and places the skirt within the lamellar pocket. The second stage of the surgical process consists of opening the anterior covering layers about 12 weeks post-implant, which exposes the anterior surface of the AlphaCor optic and allows light transmission into the eye. The AlphaCor is available in two different powers: AlphaCor-A™ for aphakic eyes and AlphaCor-P™ for phakic and pseudophakic eyes. AlphaCor-A™ delivers additional positive power to compensate for the absence of a lens in the aphakic eye.

SUBSTANTIAL EQUIVALENCE:
The AlphaCor keratoprosthesis was shown to be substantially equivalent to the Dohlman Doane Type I keratoprosthesis. Both devices are indicated as permanent implantable keratoprostheses for eyes that are not corneal transplant candidates and are made of materials that have been proven to be biocompatible.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 9 2002

Argus Biomedical Pty Ltd.
c/o Barbara S. Fant, Pharm.D.
Clinical Research Consultants
3307 Clifton Avenue
Cincinnati, OH 45220

Re: K013756
Trade/Device Name: AlphaCor™-A and AlphaCor™-P Artificial Cornea
Regulation Number: 21 CFR 886.3400
Regulation Name: Keratoprosthesis
Regulatory Class: II
Product Code: HQM
Dated: June 27, 2002
Received: June 28, 2002

Dear Dr. Fant:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 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); 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.
This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

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

510(k) Number (if known): K013756

Device Name: AlphaCor; AlphaCor-P; AlphaCor-A

Indications For Use:

Adult patients with corneal opacity not suitable for standard penetrating keratoplasty with donor tissues, or where donor tissue has been declined, or where adjunctive measures required to prevent graft rejection are medically contraindicated.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

Donna R. Lechner

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K013756