



New Device Approvals

AquaFlow™ Collagen Glaucoma Drainage Device - Model CGDD-20 - P000026

This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name: AquaFlow™ Collagen Glaucoma Drainage Device, Model CGDD-20
Manufacturer: STAAR Surgical Company
Address: 1911 Walker Avenue, Monrovia, CA 91016
Approval Date: July 12, 2001
Approval Letter: <http://www.fda.gov/cdrh/pdf/p000026a.pdf>

What is it? The AquaFlow device is used to treat open-angle glaucoma, a condition in which the pressure within the eyeball (intraocular pressure) is abnormally high. If left untreated, glaucoma can cause blindness. The device is a small cylinder made of collagen. Implanted in the eye, it helps lower the pressure by absorbing excess fluid.

How does it work? The device is designed to maintain a space under the white part of the eye (the sclera). Once placed there, it swells as it absorbs fluid in the eye. This reduces pressure within the eyeball. Later, the device begins to slowly dissolve until it is completely absorbed within 6-9 months.

When is it used? It is used in patients with open angle glaucoma where excess pressure within the eyeball cannot be completely controlled with medications.

What will it accomplish? In a U.S. clinical study, the AquaFlow™ Collagen Glaucoma Drainage Device reduced eye pressure at least as well as other, more invasive forms of treatment such as surgery. In addition, it allowed patients to reduce the number of glaucoma medications they needed to control their eye pressure.

When should it not be used? The patient and surgeon should consider the potential risks and benefits in deciding whether or not to implant this device. The Aquaflow™ device should not be used in patients who

- have known allergic reactions to collagen or products derived from pigs,
- have other types of glaucoma, or
- can control their glaucoma with medications.

Additional information: Summary of Safety and Effectiveness is available at:
<http://www.fda.gov/cdrh/pdf/p000026.html>

(Updated 08/27/2001)