K970233

# 510(k) Summary

OCT - 8 1997

## GELBFISH ENDOVAC SYSTEM

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|---|---|
| Common Name: | Endovascular Suction Catheter |
| Sponsor: | Gary A. Gelbfish, M.D.<br>2502 Avenue I<br>New York, NY 10035<br>Phone: 800-563-1463<br>Fax: 718-421-0628 |
| Contact: | Gary A. Gelbfish, M.D. |
| Prepared: | October 1, 1997 |

## A. LEGALLY MARKETED PREDICATE DEVICES

The **Gelbfish EndoVac System** is substantially equivalent to two pre-amendment devices, both endovascular suction catheters, marketed in the 1960s by the A. S. Aloe Company, St. Louis, MO, and by the Klista Company, Nashville, TN. These devices were used in general vascular surgery applications where it was necessary to remove thrombus. It is also similar to another pre-amendments suction thrombectomy device that is still marketed today by Medi-tech, the Greenfield Pulmonary Embolectomy Catheter which uses a suction mechanism for the extraction of clot from the pulmonary vasculature.

## B. DEVICE DESCRIPTION

The **Gelbfish EndoVac System** consists of a set of three main groups of components: (1) an introducer sheath with side-port for suction connection (with three-way stopcock), plus dilator and guidewire (used for initial sheath insertion), (2) a stainless steel anti-clogging/self-cleaning unit with connector for saline injection, dual check valve, tubing and syringe for saline irrigation, and (3) suction components--a fail-safe trumpet suction valve, and suction tubing. All but the stainless part are components that are presently marketed as medical devices or components. Only the stainless steel self-cleaning unit is new, and it is fabricated from medical grade stainless steel components used for blood contact applications.

## C. INDICATIONS FOR USE

The **Gelbfish EndoVac System** is intended for the percutaneous aspiration of thrombus from acutely clotted AV grafts as a part of a percutaneous thrombectomy procedure. The device incorporates an anti-clogging/self-cleaning mechanism to maintain its uninterrupted function.

The device is not (by itself) intended to restore function to clotted AV grafts. It is only used in conjunction with standard percutaneous thrombectomy procedures to facilitate the aspiration of clot from the graft. The arterial and venous anastomotic plug/clot and pathology must still be addressed by standard Fogarty and/or balloon catheter procedures. Expertise in traditional pharmoco-mechanical techniques is necessary, and may be used in conjunction with the EndoVac System.

The enclosed device is indicated for use to remove thrombus in clotted synthetic ePTFE grafts only. Its short length makes it suitable for aspiration of clot from the body of the graft. It is NOT intended to cross arterial or venous anastomoses or to be used on clot contained in native artery or vein.

## D. TECHNOLOGICAL CHARACTERISTICS

The percutaneous thrombectomy procedure in which the **EndoVac** device is used involves a series of steps, almost all of which are already part of both the radiological and surgical procedures. The only enhancement is the aspiration of clot from the graft via the introducer sheath in conjunction with the anti-clogging/self-cleaning mechanism.

The anti-clogging/self-cleaning mechanism consists of a blunt tip of the same diameter as the tip of the sheath, a short half-cylindrical tube of the same diameter as the tip, and a 22-gauge tube to inject saline just behind the tip and to provide the mechanical movement of the tip. When the tip is extended just beyond the end of the sheath, the half-cylindrical tube allows thrombus to be sucked into the sheath through its open half. When thrombus clogs the sheath during suction, the tip is withdrawn into the sheath, cutting off the interior of the sheath from the clotted graft. Saline is introduced inside the tip behind the clog and allows the sheath to be cleared, after which the tip is again extended into the open position and aspiration continues.

Clinical procedure: An introducer sheath is inserted in the venous limb of the graft pointing towards the venous anastomosis. The sideport is connected to wall suction controlled via a hand held valve. The sheath with self-cleaning mechanism is inserted into the graft, suction is

activated and the sheath is slowly pulled back, reciprocating the self-cleaning mechanism and with active irrigation as necessary.

## E. TESTING

Mechanical testing has demonstrated that the stainless steel cleaning mechanism, which is laser welded together, can withstand a pull test of 20 lbs.

A clinical study of the device showed that in 47/47 thrombectomy procedures, the **EndoVac** device successfully cleared thrombus from the graft. The study also demonstrated that the **EndoVac** device does not interfere in any way with the use of the other instruments and techniques which are required to complete the interventional radiology thrombectomy procedure.

## F. CONCLUSIONS

The **Gelbfish EndoVac System** has the same intended use, notably the aspiration of clot, as the predicate devices. Dr. Gelbfish has demonstrated through his clinical study on the device and his comparison of the device's characteristics with those of the predicate devices that it is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
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Gary A. Gelbfish, M.D.
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12300 Twinbrook Parkway, Suite 625
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OCT - 8 1997

Re: K970233
Gelbfish EndoVac System
Regulatory Class: II
Product Code: MCW
Dated: July 8, 1997
Received: July 9, 1997

Dear Dr. Gelbfish:

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. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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 the labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. 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,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

## STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: Gelbfish Endo-Vac System

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

_____ _____ Judith Connelly for J. Ryan 10/7/97

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)