

K964210



OCT 31 1997

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

CONTACT PERSON:

Laraine Pangelina
Sr. Manager, Regulatory Affairs
Target Therapeutics, Inc.
47201 Lakeview Blvd.
Fremont, CA 94538-6530

DEVICE NAME:

Retriever II Endovascular Snare Device, Class II

DEVICE DESCRIPTION:

The Retriever II (R-II) is a single use, disposable endovascular Snare. The R-II consists of a flexible core wire, radiopaque coils at the distal end of the corewire facilitate fluoroscopic visualization. Fiber strands are attached to the distal tip of the core wire. A platinum tip marker is attached at the distal end of the fibers to facilitate fluoroscopic visualization. The fibers, when manipulated, work to ensnare the misplaced coil.

INDICATIONS FOR USE:

The Retriever II is indicated for use in the retrieval of intravascular occlusion coils misplaced during interventional radiological procedures in peripheral and neurovasculature.

PREDICATE DEVICE:

Target Therapeutics' Retriever-18

TESTING in SUPPORT of SUBSTANTIAL EQUIVALENCE DETERMINATION:

The results of bench testing (tensile, turns to failure, tip flexibility, fiber retention), animal studies, and Biocompatibility testing support the substantial equivalence claims of the R-II for its intended use. Results of the bench testing, animal studies, and Biocompatibility testing in conjunction with the substantial equivalence claims as outlined in this premarket notification, effectively demonstrate that the R-II is substantially equivalent to the predicate device.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 31 1997

Ms. Linda Guthrie
Senior Regulatory Affairs Specialist
Target Therapeutics
47201 Lakeview Boulevard
P.O. Box 5120
Fremont, California 94537-5120

Re: K964210
Retriever II
Regulatory Class: II (two)
Product Code: DQO
Dated: July 28, 1997
Received: August 4, 1997

Dear Ms. Guthrie:

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) 594-4648. 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, Ph.D.
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



INDICATIONS FOR USE STATEMENT

510(k) Number: K964210

Device Name: Retriever II

Indications for Use: The Retriever II is indicated for use in the retrieval of intravascular occlusion coils misplaced during interventional radiological procedures in peripheral and neurovasculature.

A handwritten signature in black ink, appearing to read "Tan A. P.", written over a horizontal line.

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number

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