



K971395
July 14, 1997

**510(K) SUMMARY OF SAFETY AND EFFECTIVENESS,
CLASS III CERTIFICATION STATEMENT,
CERTIFICATION OF IDENTICAL MATERIALS**

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.

a) Summary of Safety and Effectiveness

CONTACT PERSON:

Roxane Baxter
Manager, Regulatory Affairs
Target Therapeutics, Inc.
47201 Lakeview Blvd.
Fremont, CA 94538-6530

DEVICE NAMES:

Please refer to Table 1 (Page 10)

DEVICE DESCRIPTIONS:

Please refer to Table 1 (Page 10)

INDICATIONS FOR USE:

Please refer to Table 2 (Pages 13 and 14)

PREDICATE DEVICES:

- Guglielmi Detachable Coil - K962503
- TRACKER Infusion Catheters - K925813
- GUIDEWIRES
 - Dasher - K950069, K915115
 - Taper - K924987, K880762
 - Seeker - K912293, K922912
 - Stubbie - K912293
- STEALTH Dilatation Catheters - K915895
- ACCESSORIES
 - Rotating Hemostatic Valve - K873971
 - Guidewire Introducer - K873972
 - Guidewire Torquer - K860840
 - Coil Pusher - K911779, K891688
 - Shaping Mandrel - K951159
 - Valve Wire - K915895, K90428
- OCCLUSION COILS
 - Fibered Platinum Coil, .035" Type - K955293
 - Berenstein Liquid Coil - K964112
 - Occlusion Coils - K914786

W9

TESTING in SUPPORT of SUBSTANTIAL EQUIVALENCE DETERMINATION:

Table 1 summarizes the testing done in support of a determination of substantial equivalence. Testing in support of this submission may be found in Section 6 beginning on page 37.

Table 1
Summary of Tests - By Product or Product Family

Product Family	Functional Tests	Chemical Degradation / Biocompatibility Tests	Sterile Barrier Test
Guglielmi Detachable Coil (GDC®)	<ul style="list-style-type: none"> • Visual / Dimensional Inspection • Detachment Time • Bushing Leak Test • Tensile Strength <p>Reference Section 6E, Page 118</p>	<p>FTIR spectragraphs generated for:</p> <ul style="list-style-type: none"> • Dacron Fiber • PTFE Bushing • Teflon Spray <p>Reference Section 6E, Page 119 and 125</p>	<p>Packaging Integrity / Microbial Challenge Test (Tracker-18 used for representative product packaging)</p> <p>Reference: Section 6E, Page 119 and Section 6F, Page 130</p>
Occlusion Coils	<ul style="list-style-type: none"> • Visual / Dimensional Inspection • Fiber Integrity <p>Reference Section 6D, Page 106</p>	<p>FTIR spectragraph generated for:</p> <ul style="list-style-type: none"> • Dacron Fiber <p>Reference Section 6D, Page 107 and 114</p>	<p>Packaging Integrity / Microbial Challenge Test (Tracker-18 used for representative product packaging)</p> <p>Reference: Section 6D, Page 107 and Section 6F, Page 130</p>
Tracker Infusion Catheters	<ul style="list-style-type: none"> • Visual / Dimensional Inspection • Tip Flexibility • Static Rupture • Tensile Strength • Coating Integrity <p>Reference Section 6B, Page 65</p>	<p>FTIR spectragraphs generated for:</p> <ul style="list-style-type: none"> • Polyethylene • Polyethylene w/ Silicone Coating • Silicone Coating • Polypropylene • Polycarbonate Hub • Polyurethane Luer Fitting • Polycarbonate RHV <p>Reference Section 6B, Page 67 and 76</p>	<p>Packaging Integrity / Microbial Challenge Test (Tracker-18 used for representative product packaging)</p> <p>Reference: Section 6B, Page 67 and Section 6F, Page 130</p>

50

Table 1 (cont.)

Summary of Tests - By Product or Product Family

Product Family	Functional Tests	Chemical Degradation / Biocompatibility Tests	Sterile Barrier Test
STEALTH Balloon Dilatation Catheters	<ul style="list-style-type: none"> • Visual / Dimensional Inspection • Static Rupture • Valve Wire Sealing • Silicone Coating Integrity <p>Reference Section 6C, Page 90</p>	<p>FTIR spectragraphs generated for:</p> <ul style="list-style-type: none"> • Silicone Coating • Polyethylene <ul style="list-style-type: none"> - distal shaft - proximal shaft - balloon tubing <p>Reference Section 6C, Page 90 and 99</p>	<p>Packaging Integrity / Microbial Challenge Test (Tracker-18 used for representative product packaging)</p> <p>Reference: Section 6C, Page 90 and Section 6F, Page 130</p>
Guidewires	<ul style="list-style-type: none"> • Visual / Dimensional Inspection • Tip Stiffness • Tensile Strength • Turns to Failure • Teflon Adhesion <ul style="list-style-type: none"> - Spray coating - Laminated tubing <p>Reference Section 6A, Page 39</p>	<p>FTIR spectragraphs generated for:</p> <ul style="list-style-type: none"> • Teflon Spray Coating • Teflon Tubing, Laminated • Silicone Coating <p>Reference Section 6A, Page 41 and 59</p>	<p>Packaging Integrity / Microbial Challenge Test (Tracker-18 used for representative product packaging)</p> <p>Reference: Section 6A, Page 41 and Section 6F, Page 130</p>
<u>Accessories</u>			
Guidewire Torquer	<ul style="list-style-type: none"> • Visual / Dimensional Inspection • Component Compatibility Test • Grip Test <p>Reference Section 6A, Page 40</p>	N/A - no body contact	<p>Packaging Integrity / Microbial Challenge Test (Tracker-18 used for representative product packaging)</p> <p>Section 6F, Page 130</p>
Guidewire Introducer	<ul style="list-style-type: none"> • Visual / Dimensional Inspection • Introducer Pull Test <p>Reference Section 6A, Page 40</p>	N/A - no body contact	"

SI

Table 1 (cont.)
Summary of Tests - By Product or Product Family

Product Family	Functional Tests	Chemical Degradation / Biocompatibility Tests	Sterile Barrier Test
<u>Accessories (cont.)</u> Rotating Hemostatic Valve	<ul style="list-style-type: none"> • Visual / Dimensional Inspection Reference Section 6B, Page 84	FTIR spectrograph generated for: <ul style="list-style-type: none"> • Polycarbonate Reference Section 6B, Page 84 and 94	Packaging Integrity / Microbial Challenge Test (Tracker-18 used for representative product packaging) Reference: Section 6F, Page 130
Shaping Mandrel	Covered under testing done for guidewires. Reference Section 6A, Page 66	Covered under testing done for guidewires. Reference Section 6A.	"
Valve Wire	Covered under testing done for guidewires. Reference Section 6A.	FTIR spectrographs generated for: <ul style="list-style-type: none"> • Teflon coating • Silicone coating Covered under testing done for guidewires. Reference Section 6A.	"
Coil Pushers	<ul style="list-style-type: none"> • Visual / Dimensional Inspection • Tip Stiffness • Tensile Strength • Turns to Failure • Teflon Adhesion <ul style="list-style-type: none"> - Spray coating - Laminated tubing Reference Section 6A, Page 39	FTIR spectrograph generated for: <ul style="list-style-type: none"> • Teflon coating Covered under testing done for guidewires. Reference Section 6A.	"



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Roxane Baxter
Manager, Regulatory affairs
Target Therapeutics
47201 Lakeview Boulevard
Fremont, California 94538-6530

JUL 14 1997

Re: K971395
Various Class II and Class III devices (add shelf life)
Regulatory Class: II and III (Two and Three)
Product Codes: 74 DQX, 74 GBK, 74 LIT, 74 KRD, 74 DYG, and
84 HCG
Dated: April 14, 1997
Received: April 15, 1997

Dear Ms. Baxter:

We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices are 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

Page 2 - Ms. Roxane Baxter

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 (i.e., with a shelf life of either 36 or 50 months, depending on the device). 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, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2

TARGET THERAPEUTIC

510(k) Number (if known): K971395Device Name: See table belowIndications For Use: See table below

Device Name	Indications
Guglielmi Detachable Coils (GDC®)	For embolizing certain intracranial aneurysms that - because of their morphology, their location, or the patient's general medical condition - are considered by the treating neurosurgical team to be a) very high risk for management by traditional operative techniques, or b) inoperable; and for embolizing other vascular malformation such as arteriovenous malformations and arteriovenous fistulae of the neuro vasculature. The GDC is also intended for arterial and venous embolizations in the peripheral vasculature.
Occlusion Coils: Fibered Platinum Coil, .035" Type Berenstein Liquid Coil	For arterial and venous embolizations in the peripheral vasculature For the embolization of vascular malformations of the peripheral, coronary and neuro vasculature.
Occlusion Coils (except Fibered Platinum Coil .035" Type and Berenstein Liquid Coil)	Coils are intended to obstruct or reduce blood flow in the peripheral and neurovasculature. They are intended for use in the interventional radiologic management of arteriovenous malformations and arteriovenous fistulas when devascularization prior to definitive surgical resection is desirable.
Guidewires	Target Therapeutics Steerable Guidewires are designed to assist in the delivery of Tracker Infusion Catheters to selected vascular sites.
Tracker® Infusion Catheter	Tracker Infusion Catheters are designed to assist in the delivery of diagnostic agents, such as contrast media, and therapeutic agents, such as occlusion coils, into the peripheral, coronary, and neurovasculature.
Stealth® Dilatation Catheter	The Stealth Dilatation Catheter System is intended for the dilatation of peripheral vasculature (PTA). This device is no intended for use in the coronary arteries.
Coil Pusher	The coil pusher is a guidewire-like device consisting of a stainless steel wire with a radiopaque gold marker at its tip. The coil pusher is intended to be used by the physician in deploying the coil to the site.
Guidewire Introducer	The guidewire introducer consists of a cannula and luer used to introduce guidewires into catheter hubs or hemostatic valves.
Guidewire Torquer	The guidewire torquer was developed to enhance control of torqueable guidewires during intravascular placement.
Rotating Hemostatic Valve	To maintain a fluid tight seal at the point of entry when a guiding catheter or sheath is used to support the placement of a therapeutic or diagnostic catheter.
Shaping Mandrel	The Shaping Mandrel is a stainless steel accessory device used by physicians to form or shape a catheter tip to suit the requirements of a particular case.
Valve Wire	The Valve Wire is used in conjunction with Stealth balloon dilatation catheters to seal the distal end of the balloon section enabling it to be inflated.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices510(k) Number K 971395Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

3