K964488

APR 21 1998

SECTION 4
510(k) SUMMARY

Contact Person
Lynn K. Bell
Regulatory Affairs/Clinical Research Assistant Manager
Target Therapeutics
47201 Lakeview Boulevard
Fremont, California 94538-6530
Telephone: 510-440-7700
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Date of Preparation

November 1, 1996

Device Name

Detachable Silicone Balloon (DSB)

Artificial Embolization Device (21 CFR 882.5950)

Device Description

The DSB consists of a silicone balloon which is inflated with contrast agent and detached via catheter at the desired site of embolization.

Indications for Use

The DSB is intended for artificial embolization of symptomatic carotid cavernous fistulae in patients for whom, in the judgment of the neurosurgical management team, other medical or neurosurgical means would not be indicated.

Device Testing

Biocompatibility testing was performed and the results demonstrated the device to be safe for its intended use.

Functional bench testing included cycle testing, rupture testing, pressure volume testing, detachment force testing, inflation-deflation cycle rate testing and catheter insertion valve testing. The results of these tests demonstrated the DSB to be safe for its intended use.

Predicate Devices

- Target Therapeutics Detachable Platinum Coil (GDC)
- Target Therapeutics (ITC) Radiopaque Spherical Emboli
- Target Therapeutics (ITC) Contour Emboli
- Target Therapeutics (ITC) Occlusion Balloon Catheter

Intended use, materials, manufacturing, design parameters, method of delivery and method of deployment of the DSB are equivalent, if not identical, to the predicate devices, rendering the DSB substantially equivalent.

Please refer to the comparison chart on page 4-3.

Substantial Equivalence Comparison Chart: Proposed and Predicate Devices

	Proposed	**Predicate**	**Predicate**	**Predicate**
	Detachable Silicone Balloon (DSB)	**Target Therapeutics Detachable Platinum Coil (GDC) K960705**	**Target Therapeutics (ITC) Radiopaque Spherical Emboli (RSE) K871047**	**Target Therapeutics (ITC) Contour Emboli (CE) K944354**
General description	Artificial embolization device	Artificial embolization device	Artificial embolization device	Artificial embolization device
Indications for use	Occlusion of carotid cavernous fistulae	Occlusion of certain intracranial aneurysms and neurovascular arteriovenous malformations and arteriovenous fistulas	Occlusion of cerebral arteriovenous malformations, vascular aneurysms, hemangiomas and vascular occlusion	Occlusion of hypervascular tumors and arteriovenous malformations
Device function	Creates a physical barrier to effect vascular occlusion	Creates a physical barrier to effect vascular occlusion	Creates a physical barrier to effect vascular occlusion	Creates a physical barrier to effect vascular occlusion
Material	Silicone elastomer	Platinum/Tungsten alloy	Silicone elastomer	Polyvinyl Alcohol
Delivery method	1.5 FR or 2.0 FR intravascular catheter	2.0 or 2.5 FR intravascular catheter	2.0 FR intravascular catheter	2.0 FR intravascular catheter
Deployment method	Controlled detachment from catheter	Controlled detachment from catheter	Injection through catheter	Injection through catheter

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 21 1998

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

Re: K964488
Trade Name: Detachable Silicone Balloon (DSB)
Regulatory Class: III
Product Code: HBZ
Dated: January 20, 1998
Received: January 21, 1998

Dear Ms.Baxter:

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 requirement, 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) 594-4595. 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,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 3

STATEMENT OF INDICATIONS FOR USE

Company name: Target Therapeutics

Device name: Detachable Silicone Balloon (DSB)

Indications for use: The DSB is intended for artificial embolization of symptomatic carotid cavernous fistulae in patients for whom, in the judgment of the neurosurgical management team, other medical or neurosurgical means would not be indicated.

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K964488