

K965071

APR 21 1998

**SECTION 4**  
**510(k) SUMMARY**

Contact Person

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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 14, 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 Detachable Silicone Balloon (DSB) is intended for artificial embolization of the internal carotid artery in the presence of certain intracranial aneurysms 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**

	<u><b>Proposed</b></u>	<u><b>Predicate</b></u>	<u><b>Predicate</b></u>	<u><b>Predicate</b></u>
	<b>Detachable Silicone Balloon (DSB)</b>	<b>Target Therapeutics Detachable Platinum Coil (GDC) K960705</b>	<b>Target Therapeutics (ITC) Radiopaque Spherical Emboli (RSE) K871047</b>	<b>Target Therapeutics (ITC) Contour Emboli (CE) K944354</b>
<u><b>General description</b></u>	Artificial embolization device	Artificial embolization device	Artificial embolization device	Artificial embolization device
<u><b>Indications for use</b></u>	Occlusion of internal carotid artery in presence of certain aneurysms	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
<u><b>Device function</b></u>	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
<u><b>Material</b></u>	Silicone elastomer	Platinum/Tungsten alloy	Silicone elastomer	Polyvinyl Alcohol
<u><b>Delivery method</b></u>	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
<u><b>Deployment method</b></u>	Controlled detachment from catheter	Controlled detachment from catheter	Injection through catheter	Injection through catheter



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: K965071  
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.

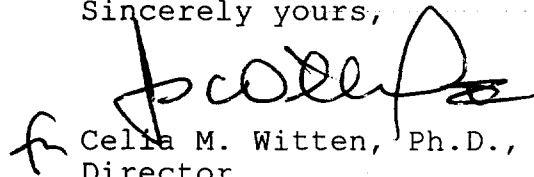
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - Ms. Baxter

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,

A handwritten signature in black ink, appearing to read "C. Witten", is written over the typed name. The signature is stylized and cursive.

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**

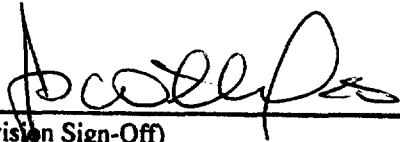
Company name: Target Therapeutics

Device name: Detachable Silicone Balloon (DSB)

Indications for use: The Detachable Silicone Balloon (DSB) is intended for artificial embolization of the internal carotid artery in the presence of certain intracranial aneurysms in patients for whom, in the judgment of the neurosurgical management team, other medical or neurosurgical means would not be indicated.

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

X



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

510(k) Number K965071