K962230

II 510(k) Summary

DEC 16 1996

B. Braun Medical, Inc
824 Twelfth Avenue
Bethlehem, PA 18018
(610) 691-5400

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CONTACT: Mark S. Alsberge, Regulatory Affairs Manager

PRODUCT NAME: Celsite™ Port wit Preconnected Catheter

TRADE NAME: Celsite™ Implanted Ports & Catheters

CLASSIFICATION NAME: General Hospital Devices
Class III, 80 LJT
Implanted Port & Catheter,
Intravascular, Infusion

SUBSTANTIAL EQUIVALENCE[1] TO:

510(k) number	Name	Applicant
K952548	CELSITE™ Venous Access System	B. Braun Medical

DEVICE DESCRIPTION:

The Celsite™ Port with Preconnected Catheter is an implanted port with a catheter system attached which allows safe , repeated access to the patient's bloodstream. The port chamber and catheter design can be used for the administration of medications and fluids.

[1] The term "substantially equivalent" as use herein is intended to be a determination of substantial equivalence from a FDA -regulatory point of view under the Federal Food, Drug, and Cosmetic Act and relates to the fact that the product can be marketed without premarket approval or reclassification. These products may be considered distinct from a patent point of view. The term "substantially equivalent" is not applicable to and does not diminish any patent claims related to this product or the technology used to manufacture the product.

MATERIAL:

The Celsite™ Port with Preconnected Catheter is composed of materials that have been tested in accordance with Tripartite Guidance for Plastics and determined to be suitable for the intended use of this product.

SUBSTANTIAL EQUIVALENCE:

B.Braun has marketed the CELSITE™ Venous Access System since it's clearance by the FDA in 1995 (K952548). The Celsite™ Port with preconnected catheter has the same intended use and functions in the same manner as the previous celsite™ ports. Connecting the catheter during insertion or having the catheter preconnected is a matter of physician preference and has no impact on the safety or effectiveness of the device.

The implant bodies and catheters of the system are made of materials identical to those available in the original submission.

Currently marketed ports incorporate features and are available from a number of manufacturers. A review of the current literature and MDRs indicate that there are no additional risks or concerns associated with this modification to the port designs.

SAFETY AND EFFECTIVENESS:

The manufacturing site, B.Braun Celsa in France, is scheduled to be inspected by the FDA in early June of this year and has passed its previous inspection in 1995.

Implanted ports for intravascular access have become quite common with tens of thousands implanted yearly. Considering the number of ports implanted yearly verses the number of MDRs, implanted ports have demonstrated themselves on the whole to be safe and effective devices.