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510(k) Summary of Substantial Equivalence:

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Device:

Trade Name:	TARGET Vital-Port® Vascular Access System
Common/Usual Name:	Implantable Vascular Access System, Implanted Infusion Port
Proposed Classification:	Implanted Subcutaneous Intravascular Catheter

Predicate Devices:
The TARGET Vital-Port® Vascular Access System has the same intended use, design, and materials of construction as predicate Vital-Port® systems manufactured by COOK Vascular™ Incorporated.

Device Description:
The TARGET Vital-Port® Vascular Access System is for use in patient therapy requiring long-term vascular access for infusion therapy and/or blood sampling. The device is supplied sterile and is intended for one-time use. The construction materials comprising the TARGET Vital-Port® Vascular Access System are identical to those used in predicate Vital-Port® systems. Reasonable assurance of biocompatibility of the materials comprising this device is provided by their established history of use in medical product manufacturing.

Substantial Equivalence:
The TARGET Vital-Port® Vascular Access System will be manufactured according to specified process controls and a Quality Assurance Program, undergoing packaging and sterilization procedures similar to devices currently marketed and distributed by COOK Vascular™ Incorporated. This device is similar with respect to indications for use, materials and physical construction to predicate devices in terms of section 510(k) substantial equivalency.

510(K) Summary Of Safety And Effectiveness

Implanted subcutaneous intravascular catheter systems for central vessel access are useful since repeatedly puncturing veins and arteries for injection, infusion or blood sampling results in vessel wall damage, vessel stenosis and occlusion, and eventual obliteration of usable vessels. Injection of certain drugs, especially chemotherapeutic agents, causes damage to the vessel wall because of the high concentration of the drug before adequate mixing occurs in the blood stream. The use of central vessel catheters reduces the number of punctures required for repeated vessel access and enables injection into major veins and arteries to protect peripheral vessels. Two types of central vessel catheters are implanted catheters with an externalized end, and totally implantable systems. This summary focuses on totally implanted vascular access systems comparable to the TARGET Vital-Port® Vascular Access System.

Totally implantable vascular access systems consist of a port reservoir or chamber with an attached catheter. The port reservoir is covered by a self-sealing silicone rubber septum through which fluids are administered or withdrawn. The attached catheter is surgically placed in the targeted vessel and the port reservoir is implanted under the skin; the system is accessed using a non-coring needle.

Clinical use of totally implantable vascular access systems has been described since the early 1980's. These systems have been used for all classes of antineoplastic drugs, blood products, and TPN (total parenteral nutrition). Reported advantages of the totally implantable vascular access system as compared to external catheters include decreased risk of infection, patient acceptance due to improved appearance, decreased patient responsibility, and freedom of activity when the port is not in use. Although

the implantable vascular access systems currently marketed are available in various sizes and materials, the indications for use and fundamental design of the systems are substantially equivalent.

Studies have been performed comparing groups of patients having totally implantable vascular access systems and groups of patients having external percutaneous catheters which have a long history of medical use. These patient groups needing long-term venous access were analyzed for major differences in complications, patient acceptance, and costs of long-term maintenance. Reported complications for these devices included infection, venous thrombosis, catheter occlusion and catheter breakage. In these studies, the complication rate of patients having implantable vascular access systems was notably lower than that of patients having percutaneous catheters.[1-3] Comparative studies also indicated that implantable vascular access systems were more readily accepted by the patient than were percutaneous catheters due to ease of maintenance, comfort and overall acceptance.[1,3] Costs of implantable vascular access systems and percutaneous catheters were found comparable over the short-term,[3] however, beyond a six month duration, costs were reportedly lower for maintaining implantable vascular access systems due to the daily catheter care and heparin flushing required by the percutaneous catheters.[1,3] Results from these comparative studies show favor of use of the implantable vascular access system over the percutaneous catheters in patients receiving prolonged intravenous therapy.

Given the acceptance of use by both physicians and patients in the comparative studies with percutaneous catheters, a number of articles have been published in which the long-term performance of implantable vascular access systems has been assessed.

Indications for use of these systems have included the administration of chemo-therapeutic agents, intravenous fluids, antibiotics, blood and blood products, and blood withdrawal. Because of the historical experience and the large number of articles published, the information available pertaining to the use of totally implantable vascular access systems is extensive. The following table summarizes types and causes of safety and/or effectiveness problems to which totally implantable vascular access systems similar to the TARGET Vital-Port® Vascular Access System are susceptible, and literature citations upon which the safety and effectiveness summary is based. This summary includes a review of 16 published articles dating from 1985 to 1991. The feasibility and efficacy for use of the TARGET Vital-Port® Vascular Access System is shown in the clinical use and performance of these comparable totally implantable systems.

In addition to the complications reported in these publishings, there are numerous potentially occurring complications which are associated with any surgically implanted device for long-term usage. These potential complications include device reaction (e.g., fibrotic tissue encapsulation and allergies to the bio-materials), acute complications associated with any surgical procedure (e.g., pain, blood loss, hematoma, hemothorax, air embolism, cardiac tamponade), and complications associated with chronic use (e.g., implant rejection, endocarditis, damage to the port-catheter system, and system dislodgement).

The majority of complications associated with totally implantable vascular access systems may be minimized using meticulous care and monitoring the patient

closely. The history of clinical use of implantable vascular access systems shows its suitability for long-term intravascular therapy.

SUMMARY TABLE
TYPES AND CAUSES OF SAFETY AND/OR EFFECTIVENESS PROBLEMS OF TOTALLY IMPLANTABLE VASCULAR ACCESS SYSTEMS

PROBLEM	CAUSE	COMMENT	REF.
Local infection or catheter-related sepsis	May result from insufficient use of aseptic technique in accessing port, or from bacterial colonization along catheter.	Infection can usually be resolved with local care or systemic antibiotics. Meticulous attention to sterile technique upon port access may minimize occurrence.	1,3-6,14-16
Skin erosion or necrosis	Causes include inadequate implantation depth of port reservoir, toxic drug extravasation, and port pocket infection.	Place port reservoir a minimum depth of 5 mm. Monitor closely for signs of drug extravasation and local infection.	5,6,15
Venous thrombosis	Primarily due to presence of a foreign body.	May be resolved with anticoagulant treatment, as with streptokinase, heparin, or Coumadin.	4-6,14,15
Occlusion	Causes include thrombin formation, drug crystallization, catheter kinking due to inadequate port anchoring, and catheter compression between first rib and clavicle.	Confirm placement of catheter tip in area of high blood flow. Periodic flushing is important to minimize occurrence. Changing patient position may resolve symptoms. If necessary, treat with streptokinase, urokinase, or heparin.	1,3-6,11,14,15
Extravasation	Causes include needle dislodgement upon port access, disconnection between port and catheter, development of thrombosis at catheter tip which may cause retrograde flow, and catheter fracture.	Confirm complete needle entry into port chamber. Monitor for evidence of catheter damage or catheter-to-port disconnection, using radiographic techniques as necessary.	3-6,9,14,15
Catheter migration	Catheter tip may drift between jugular and SVC due to pressure changes within thoracic cavity or change in anatomic position.	Tip may shift and return to initial position in SVC with no intervention. Otherwise, radiographic techniques may be used, if necessary, to reposition catheter.	4,14,15
Catheter embolization	Catheter separation from port may be a result of disconnection, or catheter fracture due to compression between first rib and clavicle.	Use more lateral insertion to avoid catheter compression. If compression is evident, radiologically monitor patient. Upon system placement, confirm catheter-to-port connection.	4,6-8,10-14,15
Difficult access	May occur in obese patients or if excessive fatty tissue develops on chest wall.	Place port reservoir at supported location, and at appropriate depth.	3,15
Needle phobia	Reported to occur primarily in patients unfamiliar with device use.	Familiarity of use typically resolves fear over time.	3
Pneumothorax	Reported as result of surgical procedure.	Potential complication associated with surgical procedure. Use careful technique in placing system, and monitor patient closely.	5,6,15
Cardiac Arrhythmia	Reported during surgical placement of system.	Potential complication associated with surgical procedure. Continuously monitor patient closely throughout procedure. Pharmaceutic or electrical intervention may be required.	15
Arterial Puncture	Reported during surgical placement of system.	Potential complication associated with surgical procedure. Use careful technique in placing system, and monitor patient closely.	15

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