

K190185 Phasix ST Mesh with Open Positioning SystemJun 12, 2019
131 days to decisionK190185 · Product code: **OWT** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k190185/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Absorbable, Abdominal Hernia (OWT)
Date received	Feb 1, 2019
Decision date	Jun 12, 2019
Days to decision	131 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	C.R. Bard, Inc.
Location	Covington, GA, US
Contact	Shirin Mate
Website	https://www.bd.com
510(k) history	644 submissions · 609 cleared · 1976-2026

C.R. Bard, Inc. is a developer, manufacturer, and marketer of medical technologies headquartered in Covington, US. The company specializes in vascular medicine, urology, oncology, and surgical specialty devices. C.R. Bard maintains a strong FDA 510(k) regulatory track record with FDA 510(k) cleared devices from total submissions spanning 1976 to 2026. The company's portfolio encompasses cardiovascular devices, gastroenterology and urology products, and general surgical technologies. Recent clearances include temporary pacing electrode catheters, thrombectomy systems, and ...

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Device record: <https://www.510kdatabase.net/k190185/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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