

K252648 Niti-S SPAXUS StentMar 13, 2026
204 days to decisionK252648 · Product code: **PCU** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k252648/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pancreatic Stent, Covered, Metallic, Removable (PCU)
Date received	Aug 21, 2025
Decision date	Mar 13, 2026
Days to decision	204 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Taewoong Medical Co., Ltd.
Location	Gyeonggi-Do, KR
Contact	Yongjin "Jeff" Kim
510(k) history	15 submissions · 11 cleared · 2005-2026

REGULATORY CONSULTANT

Consulting firm	Biologics Consulting Group
Contact	Matthew Krueger

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k252648/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026