

K183035 Percutaneous Entry Set, Skinny Needle(R) with Chiba Tip, Disposable Two-part Trocar NeedleMay 17, 2019
197 days to decisionK183035 · Product code: **LJE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k183035/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - K
Submission type	Traditional
Device classification	Catheter, Nephrostomy (LJE)
Date received	Nov 1, 2018
Decision date	May 17, 2019
Days to decision	197 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Cook Incorporated
Location	Bloomington, IN, US
Contact	Yan Li
510(k) history	175 submissions · 153 cleared · 2006-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k183035/> 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 June 28, 2026