

K261529 Micropuncture Kit / Micropuncture Access Kit /
Micropuncture Introducer Set/ Microintroducer Kit /
Microintroducer Kit (SIS05C)

Jul 6, 2026
59 days to decision

K261529 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k261529/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	May 8, 2026
Decision date	Jul 6, 2026
Days to decision	59 days
Third-party review	No
Summary / Statement	Summary
Other names	Micropuncture Kit / Micropuncture Access Kit / Micropuncture Introducer Set / Microintroducer Kit / Microintroducer Kit (IS01); Introducer Kit / Microintroducer Kit / Introducer Set /Microintroducer Set / Micro Introducer Sheath Set / Introducer Sheath Set (NIS04)

APPLICANT

Company	Hartman Medical Group, LLC
Location	Birmingham, AL, US
Contact	Pooja Kannam
510(k) history	1 submissions · 1 cleared · 2026-2026