

K212982 Medispine - Spinal Needle, Glospine - Spinal NeedleJul 29, 2022
315 days to decisionK212982 · Product code: **BSP** · Anesthesiology
Source: <https://www.510kdatabase.net/k212982/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Conduction, Anesthetic (w/wo Introducer) (BSP)
Date received	Sep 17, 2021
Decision date	Jul 29, 2022
Days to decision	315 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Global Medikit Limited
Location	Dehradun, IN
Contact	Karun Narang
510(k) history	2 submissions · 2 cleared · 2020-2022

REGULATORY CONSULTANT

Consulting firm	Alceon
Contact	Atonu Dutta

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212982/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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