

FDA Home³ Medical Devices⁴ Databases⁵

510(k) Premarket Notification

6510(k)⁷DeNovo⁸Registration &

Adverse

Recalls 11 PMA 12 HDE 13 Classification 14 Standards 15

Listing⁹

Events¹⁰

CFR Title 21¹⁶Radiation-Emitting Products¹⁷X-Ray Assembler¹⁸Medsun Reports¹⁹CLIA²⁰TPLC²¹

New Search Back To Search Results

Device Classification Name Catheter, Intravascular, Therapeutic, Short-Term Less Than 30 Days²²

510(k) Number K210037

Device Name Pluski Safe 1 Safety IV Catheter

Mediplus (India) Limited

Applicant

1261-1262, M.I.E. Part B, Bahadurgarh-124507 Haryana (India)

Bahadurgarh, IN 124507

Applicant Contact

SuperSearch

Alka Goel

Mediplus (India) Limited Correspondent

1261-1262, M.I.E. Part B, Bahadurgarh-124507 Haryana (India)

Bahadurgarh, IN 124507

Correspondent Contact

Alka Goel

Regulation Number

880.5200²³

Classification Product Code

FOZ²⁴

Date Received

01/06/2021

Decision Date

03/25/2022

Decision

Substantially Equivalent (SESE)

Regulation Medical Specialty General Hospital

General Hospital

510k Review Panel

Summary

Summary²⁵

Type Reviewed by Third Party **Traditional**

Combination Product

No No

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14. /scripts/cdrh/cfdocs/cfPCD/classification.cfm