FDA

510(k) Premarket Notification

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Device Classification Name	Catheter, Intravascular, Therapeutic, Short-Term Less Than 30 Days[22]
510(k) Number	K210037
Device Name	Pluski Safe 1 Safety IV Catheter
Applicant	Mediplus (India) Limited 1261-1262, M.I.E. Part B, Bahadurgarh-124507 Haryana (India) Bahadurgarh, IN 124507
Applicant Contact	Alka Goel
Correspondent	Mediplus (India) Limited 1261-1262, M.I.E. Part B, Bahadurgarh-124507 Haryana (India) Bahadurgarh, IN 124507
Correspondent Contact	Alka Goel
Regulation Number	880.5200[23]
Classification Product Code	FOZ[24]
Date Received	01/06/2021
Decision Date	03/25/2022
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	General Hospital
510k Review Panel	General Hospital
Summary	Summary[25]
Type	Traditional
Reviewed by Third Party	No
Combination Product	No

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