

K233794 Insulin SyringeMar 6, 2024
99 days to decisionK233794 · Product code: **FMF** · General Hospital
Source: <https://www.510kdatabase.net/k233794/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Syringe, Piston (FMF) |
| Date received | Nov 28, 2023 |
| Decision date | Mar 6, 2024 |
| Days to decision | 99 days |
| Third-party review | Yes |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Spm Medicare Pvt. , Ltd. |
| Location | Gautam Budh Nagar, IN |
| Contact | Vipin Panwar |
| 510(k) history | 2 submissions · 2 cleared · 2023-2024 |

REGULATORY CONSULTANT

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| Consulting firm | Regulatory Technology Services, LLC |
| Contact | Prithul Bom |

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/k233794/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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