FDA 510(k) Premarket Notification

**CLEARED**

# K230263 Finesse™ Injectable PTA Balloon Dilatation Catheter

May 26, 2023
115 days to decision

K230263 · Product code: **LIT** · Cardiovascular
Source: https://www.510kdatabase.net/k230263/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Catheter, Angioplasty, Peripheral, Transluminal (LIT) |
| Date received | Jan 31, 2023 |
| Decision date | May 26, 2023 |
| Days to decision | 115 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Summa Therapeutics, LLC** |
| Location | Mountain View, CA, US |
| Contact | Timothy Murphy |
| 510(k) history | 2 submissions · 2 cleared · 2015-2023 |

## REGULATORY CONSULTANT

| | |
|---|---|
| Consulting firm | **Caraballo Consulting** |
| Contact | Elena Jugo |

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