FDA 510(k) Premarket Notification

# K191295 Percutaneous Introducer Needle

**CLEARED**

Aug 6, 2019
84 days to decision

K191295 · Product code: **GCJ** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k191295/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Laparoscope, General & Plastic Surgery (GCJ) |
| Date received | May 14, 2019 |
| Decision date | Aug 6, 2019 |
| Days to decision | 84 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Progressive Medical, Inc.** |
| Location | Fenton, MO, US |
| Contact | Roland D. Sullivan |
| 510(k) history | 1 submissions · 1 cleared · 2019-2019 |

## REGULATORY CONSULTANT

| | |
|---|---|
| Consulting firm | **Mullis & Associates, Inc.** |
| Contact | David W. Mullis |

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