FDA 510(k) Premarket Notification

# K951450 SYSTEM 2000 REPLACEMENT BATTERY, SYSTEM 2000-EXTENDED RUN REPLACEMENT BATTERY

**CLEARED**

May 17, 1995
49 days to decision

K951450 · Product code: **KIJ** · Orthopedic
Source: https://www.510kdatabase.net/k951450/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Instrument, Surgical, Orthopedic, Dc-powered Motor And Accessory/attachment (KIJ) |
| Date received | Mar 29, 1995 |
| Decision date | May 17, 1995 |
| Days to decision | 49 days |
| Third-party review | No |
| Summary / Statement | Statement |

## APPLICANT

| | |
|---|---|
| Company | **Strenumed, Inc.** |
| Location | Ventura, CA, US |
| Contact | DOUGLAS WALKER |
| 510(k) history | 1 submissions · 1 cleared · 1995-1995 |