FDA 510(k) Premarket Notification

**CLEARED**

# K013782 DISETRONIC PENFINE INSULIN INJECTION PEN NEEDLE

Nov 20, 2001
6 days to decision

K013782 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k013782/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Needle, Hypodermic, Single Lumen (FMI) |
| Date received | Nov 14, 2001 |
| Decision date | Nov 20, 2001 |
| Days to decision | 6 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Disetronic Medical Systems** |
| Location | Minnetonka, MN, US |
| Contact | DAVID E CHADWICK |
| 510(k) history | 17 submissions · 13 cleared · 1991-2001 |