FDA 510(k) Premarket Notification

# K983438 MAX IT

**CLEARED**

Feb 8, 1999
132 days to decision

K983438 · Product code: **LKY** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k983438/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Device, External Penile Rigidity (LKY) |
| Date received | Sep 29, 1998 |
| Decision date | Feb 8, 1999 |
| Days to decision | 132 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Dorea, Inc.** |
| Location | Cairo, GA, US |
| Contact | RICHARD V MOSES,JR. |
| 510(k) history | 1 submissions · 1 cleared · 1999-1999 |