FDA 510(k) Premarket Notification

# K110384 DILON 6800 ACELLA (ACELLA)

**CLEARED**

May 3, 2011
82 days to decision

K110384 · Product code: **IYX** · Radiology
Source: https://www.510kdatabase.net/k110384/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Camera, Scintillation (gamma) (IYX) |
| Date received | Feb 10, 2011 |
| Decision date | May 3, 2011 |
| Days to decision | 82 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Dilon Technologies, Inc.** |
| Location | Stillwater, MN, US |
| Contact | ELAINE DUNCAN |
| 510(k) history | 2 submissions · 2 cleared · 1999-2011 |