

**K103360 DIMENSION VISTA DIGITOXIN CALIBRATOR - DGTX
CAL**Dec 17, 2010
31 days to decisionK103360 · Product code: **JIT** · Chemistry
Source: <https://www.510kdatabase.net/k103360/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Calibrator, Secondary (JIT) |
| Date received | Nov 16, 2010 |
| Decision date | Dec 17, 2010 |
| Days to decision | 31 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|-------------------------------------------------------------|
| Company | Siemens Corp. |
| Location | Mchenry, IL, US |
| Contact | ROSE T MARINELLI |
| Website | http://www.siemens.it/ |
| 510(k) history | 66 submissions · 66 cleared · 1978-2010 |

Siemens Corp. is a global technology company headquartered in McHenry, US. The company develops medical imaging and diagnostic equipment for healthcare providers worldwide. Siemens has received FDA 510(k) clearances from total submissions. The company's regulatory focus centers on Radiology devices, which represent the dominant category of its cleared portfolio. FDA 510(k) clearances span from 1978 to 2010, establishing a significant historical record in medical device regulation. Recent cleared devices include advanced imaging systems such as CT scanners, MR systems, X-r...