FDA 510(k) Premarket Notification

# K231351 Chondral Quant

**CLEARED**

Jul 13, 2023
65 days to decision

K231351 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k231351/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Image Processing, Radiological (LLZ) |
| Date received | May 9, 2023 |
| Decision date | Jul 13, 2023 |
| Days to decision | 65 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Siemens Medical Soultions USA, Inc.** |
| Location | Hiffman Estates, IL, US |
| Contact | Milind Dhamankar |
| 510(k) history | 3 submissions · 3 cleared · 2019-2023 |