

K210039 CORE1 Implant SystemJan 7, 2022
366 days to decisionK210039 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k210039/>**SUBMISSION DETAILS**

| | |
|-----------------------|--------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Implant, Endosseous, Root-form (DZE) |
| Date received | Jan 6, 2021 |
| Decision date | Jan 7, 2022 |
| Days to decision | 366 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Cybermed, Inc. |
| Location | San Leandro, CA, US |
| Contact | Han Seul Kim |
| 510(k) history | 6 submissions · 6 cleared · 2001-2022 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k210039/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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