

K202039 Honorst Implant SystemSep 25, 2020
64 days to decisionK202039 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k202039/>**SUBMISSION DETAILS**

| | |
|-----------------------|--------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Implant, Endosseous, Root-form (DZE) |
| Date received | Jul 23, 2020 |
| Decision date | Sep 25, 2020 |
| Days to decision | 64 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Medimecca Co., Ltd. |
| Location | Anaheim, CA, US |
| Contact | Seung Yoon Lee |
| 510(k) history | 4 submissions · 4 cleared · 2013-2020 |

REGULATORY CONSULTANT

| | |
|-----------------|--------------------------------------|
| Consulting firm | LK Consulting Group USA, Inc. |
| Contact | Priscilla Chung |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k202039/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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