

K180629 DentiqGuideJul 19, 2018
132 days to decisionK180629 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k180629/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Image Processing, Radiological (LLZ) |
| Date received | Mar 9, 2018 |
| Decision date | Jul 19, 2018 |
| Days to decision | 132 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | 3D Industrial Imaging Co., Ltd. |
| Location | Gwanak-Gu, KR |
| Contact | Jin Sa Kim |
| 510(k) history | 4 submissions · 4 cleared · 2016-2020 |

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

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