

K190112 Non-Sterile Zirconia BlockDec 20, 2019
331 days to decisionK190112 · Product code: **EIH** · DentalSource: <https://www.510kdatabase.net/k190112/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Powder, Porcelain (EIH) |
| Date received | Jan 23, 2019 |
| Decision date | Dec 20, 2019 |
| Days to decision | 331 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Fine Advanced Compound Co., Ltd. |
| Location | Pyeongtaek, KR |
| Contact | Jeong Kwang-Ho |
| 510(k) history | 1 submissions · 1 cleared · 2019-2019 |

REGULATORY CONSULTANT

| | |
|-----------------|----------------|
| Consulting firm | Med.Com |
| Contact | Chris Park |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k190112/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026