

**K143431 Giselle (polymacon) Daily Wear Soft (hydrophilic)
Contact Lenses (Clear and Tinted)**Feb 20, 2015
81 days to decisionK143431 · Product code: LPL · Ophthalmic
Source: <https://www.510kdatabase.net/k143431/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Lenses, Soft Contact, Daily Wear (LPL) |
| Date received | Dec 1, 2014 |
| Decision date | Feb 20, 2015 |
| Days to decision | 81 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | I-Codi Co., Ltd. |
| Location | Buk-Gu, KR |
| Contact | Yoo Hwan Park |
| 510(k) history | 1 submissions · 1 cleared · 2015-2015 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k143431/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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