

K182392 Frozen COct 30, 2018
56 days to decisionK182392 · Product code: **GEH** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k182392/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Cryosurgical, Accessories (GEH)
Date received	Sep 4, 2018
Decision date	Oct 30, 2018
Days to decision	56 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	B.M. Tech. Worldwide Co., Ltd.
Location	Seongnam-Si, KR
Contact	Jenny Cho
510(k) history	1 submissions · 1 cleared · 2018-2018

REGULATORY CONSULTANT

Consulting firm	Mtechgroup
Contact	Dave Kim

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/k182392/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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