FDA 510(k) Premarket Notification

K182392 Frozen C

CLEARED

Oct 30, 2018
56 days to decision

K182392 · 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