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Product Classification

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Device	Peripheral Electromagnetic Field (Pemf) To Aid Wound Healing
Review Panel	Physical Medicine
Product Code	MBQ
Premarket Review	Neuromodulation and Physical Medicine Devices ⁶ (DHT5B) Neuromodulation and Physical Medicine Devices (DHT5B)
Submission Type	Contact ODE
Device Class	3
Total Product Life Cycle (TPLC)	TPLC Product Code Report ⁷
GMP Exempt?	No
Summary Malfunction Reporting	Ineligible
Implanted Device?	No
Life-Sustain/Support Device?	No
Third Party Review	Not Third Party Eligible

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