

Is Bemer Therapy FDA Approved?

Bemer therapy is not **FDA approved**, it is **FDA registered**, and approval and registration are not the same thing.

Whether this is important to differentiate is really up for individuals to decide for themselves, but the terminology of approved and registered is frequently interchanged without any acknowledgement of the differences.

The unbiased answer to the question of “Is **Bemer Therapy** FDA Approved?”, is that Bemer therapy is not FDA approved, but it is still *registered* with the FDA, has clearance to sell in the USA, and is safe for use.

See here the [Bemer FDA Registration](#) as we have displayed from a screen shot below.

Establishment Registration & Device Listing

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Proprietary Name:	Bemer Int. AG
Classification Name:	MASSAGER, THERAPEUTIC, ELECTRIC
Product Code:	ISA
Device Class:	1
Regulation Number:	890.5660
Medical Specialty:	Physical Medicine
Registered Establishment Name:	BEMER Int. AG
Registered Establishment Number:	3009102830
Owner/Operator:	BEMER Int. AG
Owner/Operator Number:	10035841
Establishment Operations:	Manufacturer

Bemer FDA Approval

Bemer FDA Approval, as commonly referred to online is actually what is known as an **FDA registration** via the [FDA 510\(K\) form](#).

An FDA 510(K) form allows the FDA to determine whether or not a device or product will fall into a category of devices which has already been reviewed by the FDA and deemed either safe or unsafe.

In the case of Bemer, they have submitted a 510(K) form to the FDA and the Bemer device has been categorized as a “**Powered Muscle Stimulator**”, as seen on the Bemer’s [510\(K\) Premarket Notification](#) (screenshot below).

This is a category of devices which the FDA has approved as safe and as such the Bemer Group has been granted permission to sell and market their product in the USA, as seen in the [FDA’s Response](#) to Bemer’s Section 510(k) premarket notification.

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Device Classification Name	Stimulator, Muscle, Powered, For Muscle Conditioning
510(K) Number	K151834
Device Name	BEMER Classic Set, BEMER Pro-Set
Applicant	BEMER Int. AG Austrasse 15 Triesen, LI 9495
Applicant Contact	Sven Bieler
Correspondent	Biomaterialize P.O. BOX 50 Tecumseh, MI 49286
Correspondent Contact	Sven Bieler
Regulation Number	890.5850
Classification Product Code	NGX
Date Received	07/06/2015
Decision Date	02/22/2017
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	Physical Medicine
510k Review Panel	Physical Medicine
Summary	Summary
Type	Traditional

BEMER **MAT** **REVIEW**