

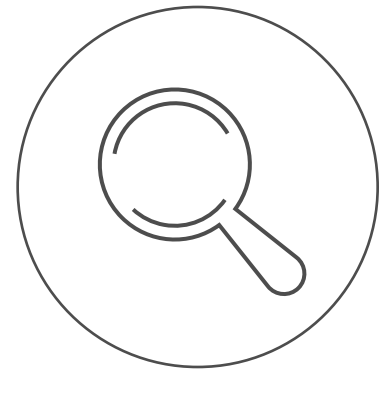
Regulatory Strategy for Successful FDA Clearance

Case Study

The Company

miha bodytec GmbH is a leading global manufacturer of whole-body electromyostimulation (EMS) devices. miha bodytec is particularly committed to ensuring that its devices are used effectively and safely in healthcare settings and professional EMS facilities.

To this end, the company maintains close ties with the scientific and research communities, as well as with users in the field. This way, miha bodytec has developed an innovative and sustainable concept for whole-body EMS specifically for health, training, and prevention. This concept is continuously being developed for new applications and therapeutic indications.

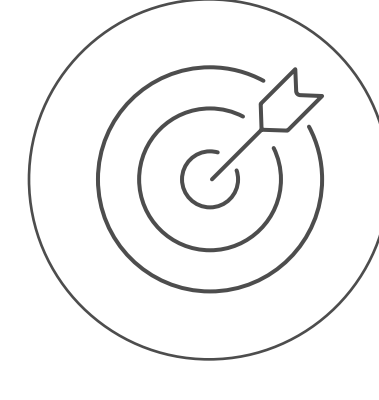


Overview

Following successful approval in numerous countries (including the EU, Brazil, and the UK), miha bodytec sought to market its miha bodytec II device in the US. This device is classified as a class II medical device according to FDA guidelines. Together with the Johner Institute, a tailor-made regulatory strategy was developed and successfully implemented to complete the 510(k) procedure and obtain FDA clearance.

As a basic prerequisite for marketing in the USA, the existing ISO 13485-compliant QM system had to be expanded to meet the FDA requirements of 21 CFR 820. Since miha bodytec has to meet the QM requirements of many countries, MDSAP certification was chosen. Together with the Johner Institute, the necessary adjustments were made, and certification was completed without any significant deviations.

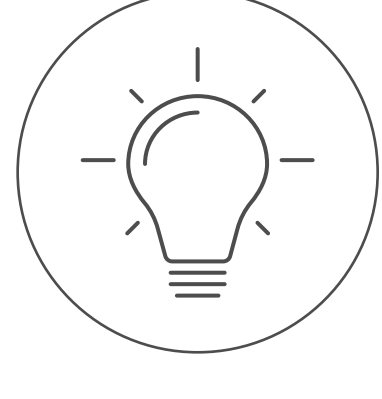
- ✓ 3x 510(k) clearance obtained
- ✓ Successful MDSAP certification



Challenge

Due to the comprehensive functionality and advanced technology (including wireless connection between the control unit and the electrodes on the body) as well as the numerous medical indications of the miha bodytec II EMS system, the search for a suitable predicate device was quite difficult as a prerequisite for 510(k) clearance.

Together with FDA experts at the Johner Institute, miha bodytec decided on a multi-stage approach, which ultimately led to three separate, consecutive 510(k) procedures, still enabling rapid market access.



Solution

In the first step, a 510(k) procedure with a limited set of indications and restricted functionality was chosen. For example, only the wired version was considered with the indication "muscle conditioning." This approach had the advantage of obtaining FDA clearance without major challenges due to several suitable predicate devices.

Shortly after obtaining successful 510(k) clearance and commencing marketing in the US, a second 510(k) was submitted to get approval for additional therapeutic indications. For this case, a predicate device strategy was chosen, utilizing two predicate devices. It was essential that all devices had the same EMS intended purpose and that there were no different questions related to safety or effectiveness resulting from technological differences. With only a few queries from the FDA, miha bodytec received its second FDA clearance in about six months and was able to use its device for further therapeutic purposes in the US.

In the third step, the focus was on the extended technological features and the different variants of the miha bodytec II system. The objective was to obtain approval for the wireless version and the mobile version m.ove. In this case, too, miha bodytec worked with the Johner Institute to develop a suitable strategy involving several predicate devices. In this case, FDA clearance was granted in record time of less than five months.

Parallel to the 510(k) submissions, miha bodytec worked with the Johner Institute to adapt the QM system. After conducting an initial comprehensive gap analysis of the requirements outlined in 21 CFR 820 and the MDSAP program, task packages were defined. Together with the quality management representative and the process owners, the changes were implemented, always with a focus on process efficiency and suitability for the company.

AN OVERVIEW OF THE SOLUTION

- ✓ Successful 510(k) clearance and start of marketing in the US
- ✓ Second FDA approval after 6 months
- ✓ Final FDA approval in record time of less than five months
- ✓ Adaptation of the QM system in parallel with the 510(k) submissions



Result

miha bodytec was able to gain market access as planned and has now established a location in the US. In its collaboration with the Johner Institute, miha bodytec particularly emphasized the Johner Institute's extensive FDA expertise.

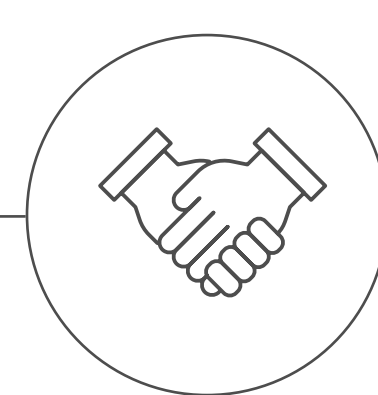
The Johner Institute's support was not limited to strategic consulting and formal submission to the FDA. With numerous experts from various disciplines, including on-site in the US, the Johner Institute also provided support with

- the biocompatibility evaluation,
- the usability study in the USA,
- electrical safety and strategy for testing the electrodes and aging tests,
- software documentation in accordance with IEC 62304 and FDA guidelines,
- risk management, and
- cybersecurity.

Conclusion

"Thanks to our close cooperation with the Johner Institute, we were able to achieve our long-standing objective of entering the US market without any problems. We benefited greatly from our partner's extensive expertise, particularly in areas where we had limited experience. In this context, the friendly interaction and uncomplicated, flexible cooperation in all matters were a particular advantage. We can still emphasize that, after years of working together on various projects, we can still rely on the same point of contact, who is familiar with our company, our individual processes, and the associated issues, and always knows how to respond. I can therefore recommend working with the Johner Institute without reservation!"

Felix Schweigert
miha bodytec GmbH



Would you like to work with us?

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