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Regulatory and compliance

The device is regulated by the FDA as a Type II medical device. This type of device will require a 510k certification.

All FDA requirements will be fulfilled by either the design manufacturing company or by a FDA consultant in the case we use a company for design that does not perform all tasks under one roof. IE:

We have two companies that can manage the whole project from design engineering through to FDA certification and manufacturing.

We are also in discussion with one company that can design and engineer the device but recommends other contractors for all other aspects of the project.



NMT
NEXXT MEDTECH



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