



Key Considerations For Selecting A Custom Transformer Supplier With Respect To FDA Section 510 (k) Approval

Introduction

Medical Original Equipment Manufacturers (OEMs) are required to submit an FDA Section 510 (k) application when they plan to market a new equipment design. Section 510 (k) of the U.S. Food, Drug and Cosmetic Act allows the FDA to determine whether the device is equivalent to similar equipment already on the market.

The custom transformers that power these medical devices, and are vital to their function, often demand extremely rare raw materials and stringent manufacturing processes that can take weeks to complete, causing lengthy delays in an OEM's production process.

To avoid these delays and get equipment into production and out to the market as quickly as possible after 510 (k) approval, it's crucial for medical OEMs to select a transformer maker that can not only design the prototype to the specifications provided, but also ensure that it's viable for full-scale production. To do this, the transformer company must have a vast array of raw materials on hand and be equipped for volume manufacturing.

Read on for tips on identifying a custom magnetics company qualified to handle complicated medical equipment applications.

The challenge is to find a magnetics supplier who can manage the complex logistics of custom transformers and meet your production deadlines.

Custom transformers are unique to each medical device. Many require hard-to-source materials or specialized manufacturing procedures, so planning for or building these transformers can take weeks of lead time.

The entire process also represents a significant outlay of time, resources, and money for the magnetics company. It takes a company with the right combination of size, expertise and supply chain connections to do the job right.

To minimize delays and speed turn-around time, choose a custom magnetics manufacturer that has the resources and experience to:

- Work closely with your regulatory team from the beginning to the end
- Have an established global network of raw material suppliers – very important for sourcing rare cores, ferrites and other materials
- Leverage existing KANBAN agreements with suppliers before FDA 510 (k) approval is final
- Invest in an extensive inventory of adhesives, bobbins, brackets, connectors, insulation, potting epoxy, tape, wires and other long lead-time commodities
- Manage the process from product development to prototype approval to full-scale production
- Implement rigorous quality control standards and documentation processes to meet FDA requirements
- Be prepared to begin production and provide delivery as soon as the FDA 510 (k) application is approved

A good magnetics supplier understands the intricacies of designing custom transformers from prototype through to production, and can avoid the “hurry-up-and-wait” issues created by the FDA 510 (k) approval process.

If this is a topic you’d like assistance with, contact Agile Magnetics:

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