PRESS RELEASE

Expanite® receives Master File for Devices (MAF) acknowledgment letter from FDA on their patented process for surface hardening of stainless steel in medical devices applications.

Expanite announces it has submitted a Master File for Devices (MAF) to the United States Food & Drug Administration (FDA) and has now been issued the submission number MAF3078.

Expanite has successfully submitted a Master File for Devices (MAF) to the Center for Devices and Radiological Health (CDRH) at the FDA for SuperExpanite®, their patented process for surface hardening of stainless steel and received an Acknowledgment letter from FDA confirming submission filing. The MAF covers necessary information such as technology, production processes and facility information, as well as test data and more. The SuperExpanite Master File has been issued submission document control number MAF3078.

"*We are very pleased to have achieved this significant milestone. The FDA registration makes it easier for our U.S. customers to obtain approval for new medical products that use Expanite surface hardening. Expanite is now able to provide a signed and named Authorization letter to our customers on their request, for the purpose of their product registrations at FDA. This is the first of many MAFs to come*" says Expanite CEO, Thomas Abel Sandholdt.

Benefits of MAF implementation

The advantages of the MAF being submitted at FDA for the manufacturers who utilize Expanite surface hardening technology and register their products at FDA are many e.g.:

- Expanite, individually, invested time to search and understand the FDA requirements for MAF submission;
- Documentation compiled, as required, and submission confirmed by FDA;
- Surface hardening technology documentation available for FDA's review as of now;
- Eliminates communication time and effort between manufacturer and Expanite on MAF build and requirements;
- Expanite responsible to maintain MAF up to date, as appropriate.

For the manufacturer's medical devices registrations purposes, the SuperExpanite Master File for Devices is now available for reference and review at FDA. Expanite shall provide MAF Authorization letter on customer requests to make Expanite technical documentation available for FDA's review in context of their product registration.

Please contact Thomas Abel Sandholdt to hear more about the FDA Master File for Devices, SuperExpanite MAF content and request a signed and named Authorization letter for your product registrations.

About Expanite A/S

Expanite offers state-of-the-art solutions for surface hardening treatment of stainless steels and titanium. With Expanite's processes, it is possible to increase the material's surface hardness tenfold while at the same time maintaining and even increasing its corrosion resistance. Expanite has a combined development and production facility near Copenhagen, Denmark, and hardening capacity in the US, Germany and China. Expanite's solutions are flexible and can be introduced directly into a customer's own production line as part of a licensing arrangement. Learn more on www.expanite.com

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