PRESS RELEASE /

EXPANITE RECIEVES MASTER FILE FOR DEVICES (MAF).

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. and solving some of their challenges with wear on the titanium parts in their racing car.

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.

Master File for Devices now available

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

Expanite is based on research since 2000 and was founded in 2010 by leading experts in materials and surface hardening. The company is headquartered in Hillerød near Copenhagen and has treatment centers in the USA, Germany and China. Expanite's solutions are flexible and can be tailored into a customer's own product line as part of a licensing agreement.