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# SINTX Submits Master Access File to FDA for Silicon Nitride-Polymer Composite Material

SALT LAKE CITY, UT, March 03, 2021 (GLOBE NEWSWIRE) -- SINTX Technologies, Inc. (NASDAQ: SINT) (“SINTX” or the “Company”) ([www.sintx.com](http://www.sintx.com)), an original equipment manufacturer (OEM) of silicon nitride ceramic, announced its FDA submission of a Master Access File (MAF) for a new Silicon Nitride – Polyetheretherketone (PEEK) composite material (SN-PEEK). The MAF can be referenced by SINTX customers toward developing new medical implant designs and products.

SN-PEEK is an innovative material platform that combines the best of two materials that are used to make spinal fusion implants, i.e., silicon nitride and PEEK. Clinical and basic science data demonstrate that SINTX’s silicon nitride facilitates faster bone healing, improves radiographic imaging, avoids metal ion release in the body, and has broad-spectrum resistance to infection. PEEK is an accepted standard polymeric biomaterial that is used worldwide, especially by spine surgeons. PEEK’s advantages include its low cost, favorable material modulus, ease of manufacturing, established clinical record, and a familiar fit and feel. The most immediate biomedical applications of this product are expected to be in the spine and craniomaxillofacial medical device markets, with other applications to follow.

SINTX said the knowledge and learning gained from this project has had many collateral benefits, such as identifying simpler and lower cost options for its materials, learning how powdered silicon nitride interacts with cells versus the as-fired material, and understanding in greater detail the surface chemistry of silicon nitride to develop newer technologies for the future. SINTX believes the SN-PEEK product is the result of the company’s commitment to innovation and looks forward to expanding its customer base with this new and exciting platform.

## **About SINTX Technologies, Inc.**

SINTX Technologies is an OEM ceramics company that develops and commercializes silicon nitride for medical and non-medical applications. The core strength of SINTX Technologies is the manufacturing, research, and development of silicon nitride ceramics for external partners. The company presently manufactures silicon nitride powders and components in its FDA registered, ISO 9001:2015 certified, ISO 13485:2016 certified, and AS9100D certified manufacturing facility.

For more information on SINTX Technologies or its silicon nitride material platform, please visit [www.sintx.com](http://www.sintx.com).

## **Forward-Looking Statements**

This press release contains forward-looking statements within the meaning of the Private

Securities Litigation Reform Act of 1995 (PSLRA) that are subject to a number of risks and uncertainties. Risks and uncertainties that may cause such differences include, among other things: incorporation of silicon nitride into personal protective equipment may not be safe or effective; volatility in the price of SINTX's common stock; the uncertainties inherent in new product development, including the cost and time required to commercialize such product(s); market acceptance of our products once commercialized; SINTX's ability to raise additional funding and other competitive developments. Readers are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date on which they are made and reflect management's current estimates, projections, expectations, and beliefs. There can be no assurance that any of the anticipated results will occur on a timely basis or at all due to certain risks and uncertainties, a discussion of which can be found in SINTX's Risk Factors disclosure in its Annual Report on Form 10-K, filed with the Securities and Exchange Commission (SEC) on March 26, 2020, and in SINTX's other filings with the SEC. SINTX disclaims any obligation to update any forward-looking statements. SINTX undertakes no obligation to publicly revise or update the forward-looking statements to reflect events or circumstances that arise after the date of this report.

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