

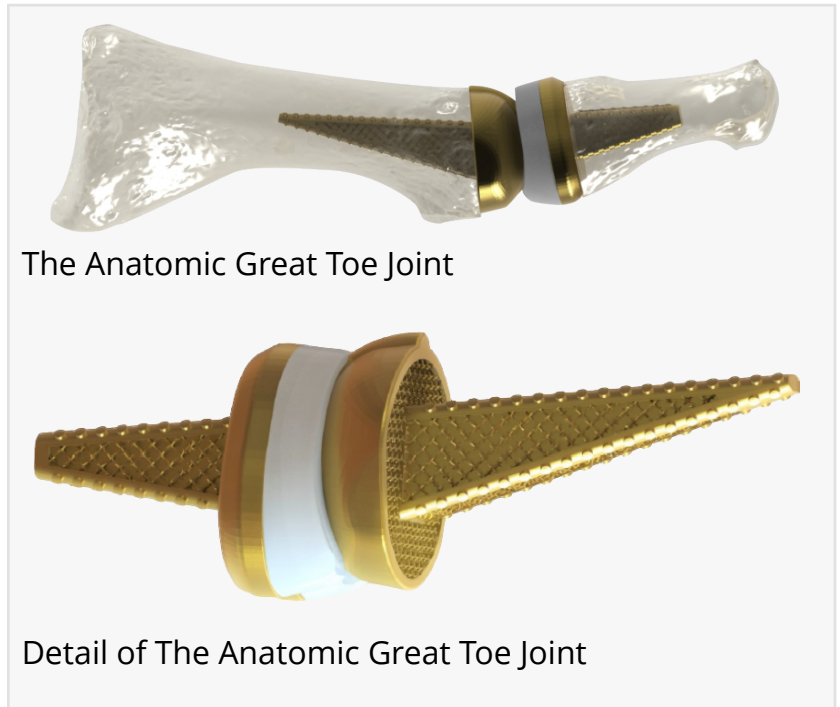
AddUp and Anatomic Implants Announce FDA 510(k) Submission for the World's First 3D Printed Toe Joint Replacement

The MTP toe joint replacement will be printed on AddUp's FormUp 350 metal 3D printer as they support Anatomic Implants on their path to FDA clearance.

CINCINNATI, OH, UNITED STATES, February 5, 2024 /EINPresswire.com/ -- [AddUp](#), global metal additive manufacturing OEM, and Anatomic Implants announced today that they are working together to submit a 510(k) for the world's first 3D printed toe joint replacement.

Anatomic Implants, a medical device startup out of Washington, DC, is the first medical device startup company to patent and develop a 1st metatarsophalangeal (MTP) joint replacement that nearly perfectly replicates the human anatomy by leveraging titanium [3D printing technology](#). The MTP toe joint is located at the base of the big toe and is one of the 3 main points used for balance. It is often the first joint in the foot to develop osteoarthritis. With the global market for 1st MTP joint reconstruction being \$500M+ annually, the market is underserved with very few products, none of which are anatomic or have the potential to support bone-in growth as well as the Anatomic Great Toe Joint. Only through the use of additive manufacturing can a porous structure be integrated into the design to promote osseointegration. Osseointegration gives implants a much higher chance of bonding to the bone, which can reduce the chances of the implant being rejected by the body. This leads to better patient outcomes after surgery.

To bring their product to market, the company has chosen AddUp's [FormUp 350](#) Powder Bed Fusion (PBF) machine to qualify the implant for submission to the FDA. The FormUp 350 stands out in its ability to produce varying complex geometries with fine detailed lattice structures, ideal for implantable medical devices. The FDA's Center for Devices and Radiological Health (CDRH) and the Center for Drug Evaluation and Research (CDER) has approved many 3D printed class II



The Anatomic Great Toe Joint

Detail of The Anatomic Great Toe Joint

medical devices through the 510(k) pathway since the mid 2000's.

“With 1st MTP joint replacement being a largely underserved market, and medical device companies building lattice structures into implantables since the mid 2000's, Dr. Nutter and I sought out to make a more anatomic design by leveraging the latest technologies adopted by the industry & FDA” explains Anatomic Implants President, David Nutter. “We were excited to partner with AddUp to achieve 510(k) clearance after learning about their proprietary 3D printing technology and seeing how it could benefit the development of the Anatomic Great Toe Joint. We look forward to leveraging the AddUp team and their expertise to validate the world's first 3D printed toe joint replacement on their FormUp 350.”



AddUp's FormUp 350 Powder Bed Fusion Machine

The 510(k) clearance process involves a comprehensive review of safety and performance data for the implant to determine if it is substantially equivalent to an implant that is already on the market. With several tests already completed and 510(k) clearance anticipated in late Q3, 2024, the future is bright for AddUp, Anatomic Implants, and the global 1st MTP market. Anatomic Implants has been hard at work on the Anatomic Great Toe Joint since its inception late 2016 and has already secured design patents in the U.S., Canada, and throughout Europe, which represents the majority of the global 1st MTP joint reconstruction market.

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*David Nutter - President,
Anatomic Implants*

AddUp has vast experience in the medical industry with global OEMs relying on the FormUp 350 for serial

production of their medical implants. The company's North American subsidiary, The AddUp Solution Center, is located in Cincinnati, OH and is ISO13485 certified. They have experience partnering with a variety of medical customers and supporting their path to FDA clearance.

“AddUp is committed to supporting the development of cutting-edge solutions for the medical

market” says AddUp Inc. Deputy CEO, Nick Estock. “Our team at the AddUp Solution Center has the expertise on FDA regulations and qualification protocols to provide a proactive approach to regulatory compliance essential for a successful 510(k) submission. We are excited to be supporting Anatomic Implants through this process to bring the first additively manufactured toe joint replacement to market.”

The Anatomic Great Toe Joint will be on display in the AddUp booth at the American Academy of Orthopaedic Surgeons (AAOS) Annual Conference in San Francisco, CA from February 13 – 15, 2024. Learn more here: <https://addupsolutions.com/event/ortho/>

About Anatomic Implants:

Anatomic Implants was founded by Johns Hopkins Surgeon Scott W. Nutter, DPM and David Nutter. Both share a passion for innovation, entrepreneurship, and helping people thrive through enabling them to walk better.

Dr. Nutter served as Chief of Podiatry at Washington Adventist Hospital (now the White Oak Medical Center) for several years. He has performed more 1st MTP joint replacements than most orthopedic surgeons in the country, and has used every total joint replacement system that has been developed for the 1st MPJ. It was through his experience as a double board-certified physician that he had a desire to create a better product to support patient needs.

David Nutter is an entrepreneur with a track record of successful startups across a variety of industries. David contracted Jalex Medical, a renowned medical device design & regulatory affairs firm, in 2017 to jumpstart the development of the Anatomic Great Toe Joint.

About AddUp:

AddUp, a joint venture created by Michelin and Fives, is a global metal additive manufacturing OEM offering multi-technology production systems, including the FormUp® range of robust and open-architecture Powder Bed Fusion (PBF) machines, as well as the BeAM Modulo and Magic lines of industrial Directed Energy Deposition (DED) machines.

AddUp's FormUp 350 PBF range is modular and scalable to provide the highest productivity while ensuring user safety. The DED machines are designed for industrial production and equipped with in-house designed and developed nozzles to provide maximum precision and very high productivity. To provide customers with a true Industry 4.0 solution, AddUp also provides a complete monitoring solution providing quality assurances after each and every build.

AddUp is headquartered in Cébazat, France, with a North American subsidiary based out of Cincinnati, Ohio and a German subsidiary based in Aachen, Germany. In addition to the machine design and manufacturing, the AddUp group also offers part production, POC production, metal AM consulting services, AM training, and design for AM, making AddUp your one-stop for metal AM. To learn more, visit: www.addupsolutions.com.

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