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**American Orthotic &  
Prosthetic Association**

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August 8, 2016

Food and Drug Administration  
Division of Dockets Management (HFA-305)  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

Submitted electronically via [www.regulations.gov](http://www.regulations.gov)

Re: Technical Considerations for Additive Manufactured Devices: Draft Guidance for Industry and Food and Drug Administration Staff

Dear Sir/Madam:

We are writing to provide comments on the publication entitled *Technical Considerations for Additive Manufactured Devices: Draft Guidance for Industry and Food and Drug Administration Staff* which was published in the *Federal Register* on May 10, 2016.

The American Orthotic & Prosthetic Association (AOPA), founded in 1917, is the largest national orthotic and prosthetic trade association with a membership that draws from all segments of the field of artificial limbs and customized bracing for the benefit of patients who have experienced limb loss, or limb impairment resulting from a trauma, chronic disease or health condition. These include patient care facilities, manufacturers and distributors of prostheses, orthoses and related products, and educational and research institutions.

AOPA's comments relative to the draft guidance document will be limited to use of additive manufacturing in the design and fabrication of external prosthetic components and orthotic devices, specifically through the use of 3 dimensional (3-D) printing. These include artificial limbs which are intended to replace missing body parts and braces which are intended to support a weakened and/or deformed body part or member.

While at present 3-D printing is a fairly new technology as far as its use in the design and fabrication of prosthetic and orthotic devices, the policies FDA has articulated in this guidance document are appropriate as there are instances where 3-D devices are being sold and introduced into commerce, and this technology is being explored more broadly as a potentially viable alternative/enhancement to traditional manufacturing processes. The use of 3-D printing appears promising as technology rapidly advances but AOPA understands the need to ensure that components and devices that are created using 3-D printing techniques must, first

and foremost, be safe and effective for the consumers who rely on these devices to perform activities of daily living. While currently limited in its commercial application, increased use and acceptance of 3-D printing as a viable means of fabrication is likely in the future.

In the draft guidance document, the FDA stated that, "It is anticipated that AM devices will generally follow the same regulatory requirements as the classification and/or regulation to which a non-AM device of the same type is subject." AOPA agrees with this statement and does not believe generally that either additional or lesser regulatory burdens should be placed on manufacturers of prosthetic components and orthotic devices solely based on the decision to utilize an additive manufacturing process into their fabrication protocols.

The majority of external prosthetic components and orthotic devices are considered class I devices by the FDA. In respect to many of these devices, the FDA classification process further articulated that they are exempt from pre-market notification requirements through the 510(K) process and most Good Manufacturing Process (GMP)/Quality System requirements, with the exception of Section 820.198 complaint files requirements. Exemptions also were provided as to some devices from device establishment registration, records and reports under section 519, e.g., MDER reports. AOPA believes that maintaining these exemptions for class I devices that are fabricated with the use of additive manufacturing techniques is a prudent course of action that will encourage the development of technology while assuring that devices created through additive manufacturing remain safe and effective for use by the general public, and maintaining consistency and a level regulatory playing field for the devices without regard to the specific method of fabrication employed by the manufacturer..

AOPA firmly believes that the manufacture of a prosthetic component or orthotic device is only a small part of the creation of an artificial limb or orthoses that meets the individual needs of a particular patient. The components that are included in the completed prosthesis or orthosis must be adjusted, and aligned by a properly educated, trained, and certified or licensed healthcare professional such as an orthotist or prosthetist.

AOPA fully supports the role of the FDA in ensuring that medical devices, including prosthetic and orthotic devices remain safe and effective, but believes the current direction of the FDA, as outlined in the draft guidance document, to not alter regulatory requirements solely as a result of the use of additive manufacturing is appropriate.

If I can be of any further assistance on this subject, please feel free to contact me at (571) 431-0876 or via e-mail at [tfise@aopanet.org](mailto:tfise@aopanet.org).

Sincerely,

A handwritten signature in blue ink, appearing to read "T. Fise".

Thomas F. Fise, JD  
Executive Director