February 13, 2023

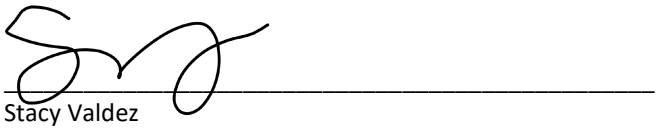
To Whom This May Concern:

In accordance with the regulatory criteria in 21 CFR 807.81(a)(3) and FDA's Guidance *Deciding When to Submit a 510(k) for a Change to an Existing Device*, the differences between the devices cleared via K201749 Arthrex SwiveLock Anchor and the Achilles SpeedBridge Implant Systems listed in **Table 1** below do not meet the threshold for requiring a new premarket notification. Therefore, the Achilles SpeedBridge Implant Systems are considered cleared via K201749.

Table 1

Part No.	Item Description
AR-9928BCK-MIS	Implant System, MIS BioComposite Knotless Achilles SpeedBridge™
AR-9928BCK-DX	Implant System, BioComposite Knotless Achilles SpeedBridge™ with JumpStart® Dressing
AR-9928BC-CP	Implant System, 3.9 mm BioComposite Achilles SpeedBridge™ with JumpStart® Dressing

Sincerely,



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