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### *Appendix*

Supplementary information was retrieved from the FDA.gov website, (<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm>), which lists the implant devices for total ankle replacements from 1976 to 2019. An archive of 132 devices for 510 (k) premarket notifications was then reviewed using the keyword search criterion “ankle”, which was further screened. Any data not relevant to total ankle replacements, such as fusion, nails, plating, cannulated screws, and braces were removed from the archive list.

The Department of Health and Human Services included a review of section 501(k) premarket of intent to market the device and deemed equivalent for the indications for use stated below. The safety and effectiveness for the use of the implant follow the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92. Summaries were only available between the period 1992 to 2019 and none was available for the public domain prior, specifically, 1976 to 1992.

A summary of each implant included the proprietary name, classification, predicate device, device description, technological characteristics comparison, substantial equivalence with non-clinical and clinical evidence and, finally, conclusions. Most of these tests for substantial equivalence for non-clinical evidence performed by engineers included but were not limited to chemical analysis, abrasion resistance, stereological evaluation, compressive strength, shear, and tensile strength; fatigue testing, MRI safety analysis, and endotoxin. Other engineering analyses performed included torsional stability, MR testing, and analysis related to displacement force, torque, artifact, RF heating testing, and pyrogenicity. (\*Appendix Table 7)

As a result, 33 pre-market implant devices for total ankle arthroplasties that met FDA standards and safety regulations from 1976 to 2019 were found. From the 33 ankle replacements approved by the FDA, 29 did not provide information on wear testing. Only four implant devices provided information regarding whether or not wear testing was performed (*K171004*, *K153008*, *K152217*, *K120906*\*). In addition, from the four devices that included wear testing in the FDA 501(k) downloadable summaries, the actual wear test rate was not reported. Moreover, while the present systematic review found only ten studies in the literature between 2006-2019, a much larger number of implant devices are readily available on pre-market and approved between 1976 and 2019, in addition to 33 approved devices.

**Supplementary Table 7: FDA 501(k) Premarket Total Ankle Replacement Patent**

Device Name	Applicant	501K #	Decision Date
Infinity Total Ankle System	Wright Medical Technology, Inc.	K181557	08/09/2018
Invision Total Ankle Revision System	Wright Medical Technology, Inc.	K180730	07/11/2018
Infinity Total Ankle System	Wright Medical Technology, Inc.	K172633	04/26/2018
<b>Hintermann Series H2 Total Ankle System***</b>	Dt Medtech Llc	K171004	11/07/2017
Invision Total Ankle Revision System	Wright Medical Technology, Inc.	K171067	09/11/2017
<b>Invision Total Ankle Revision System***</b>	Wright Medical Technology, Inc.	K153008	05/06/2016
<b>Exactech Vantage Total Ankle System***</b>	Exactech Inc	K152217	03/10/2016
Integra Total Ankle Replacement System	Ascension Orthopedics	K151459	08/31/2015
Invision Total Ankle Revision System	Wright Medical Technology, Inc.	K142117	03/25/2015
Infinity (Tm) Total Ankle System; Inbone	Wright Medical Technology, Inc.	K141740	03/05/2015
Infinity Total Ankle System	Wright Medical Technology, Inc.	K140749	04/25/2014
Inbone Total Ankle	Wright Medical Technology, Inc.	K133585	02/20/2014
Salto Talaris Total Ankle Prosthesis, Rh	Tornier Sas	K130533	05/17/2013
Infinity Total Ankle System	Wright Medical Technology, Inc.	K123954	04/01/2013
Inbone (I And II) Total Ankle Systems	Wright Medical Technology, Inc.	K123059	03/04/2013
Depuy Agility Lp Total Ankle Prosthesis	Depuy Orthopaedics, Inc.	K122395	10/31/2012
<b>Zimmer Trabecular Metal Total Ankle***</b>	Zimmer, Inc.	K120906	08/24/2012
Inbone Total Ankle System Model 20034790	Wright Medical Technology, Inc.	K103374	12/14/2010
Inbone II Total Ankle Replacement	Wright Medical Technology, Inc.	K100886	08/26/2010
Salto Talaris Total Ankle Prosthesis	Tornier	K090076	03/17/2009
Eclipse Total Ankle Implant	Kinetikos Medical, Inc.	K061749	11/22/2006
Salto Talaris Total Ankle Prosthesis	Tornier	K060544	11/13/2006
Agility Lp Total Ankle Prosthesis	DePuy Orthopaedics, Inc.	K053569	03/31/2006
Topez Total Ankle Replacement	Topez Orthopedics, Inc	K051023	11/15/2005
Agility Ankle Revision Prosthesis	DePuy, Inc.	K020541	05/20/2002
Alvine Total Ankle	DePuy, Inc.	K920802	12/17/1992
Isostation Ankle/Subtalar Machine A-100	Isotechnologies, Inc.	K844060	11/23/1984
Brigham Total Ankle Prosthesis	Howmedica Corp.	K803167	02/19/1981
Schlein Tri-Surface Ankle	Orthopedic Equipment Co., Inc.	K800530	04/02/1980
Forceps, Ankle Inserting, Con-Axial	DePuy, Inc.	K770420	03/14/1977
Components, Ankle, Trial, Con-Axial	DePuy, Inc.	K770421	03/14/1977
Ankle (Freeman-Swanson)	Medishield, Inc.	K761020	11/23/1976

Ankle Instruments (Freeman-Swanson)	Medishield, Inc.	K761021	11/23/1976
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\*\*\*Wear test reported