

Attachment 2: Examples of Bone Conduction Hearing Devices that include Surgically-Inserted Component(s) (BCHD-SI)

Sound Processor Name	Baha 5, BAHA 5 Power, BAHA 5 Super Power	Baha 5, BAHA 5 Power, BAHA 5 Super Power	BoneBridge	OSIA 2	Ponto 4, Ponto 3, 3 Power, 3 Super Power, 3 Pro Power
Manufacturer	Cochlear	Cochlear	MED-EL	Cochlear	Oticon Medical
Associated code(s)	K142907 ¹ K161123 ² K153245 ³	K142907 K161123 K153245	K191457 ⁴	K191921 ⁵ K100360 ⁵	K161671 ⁶ K190540 ⁷
Age for approved use (in years)	≥5	≥5	≥12	≥12*	≥5
Attachment mechanism	BAHA Attract Magnet and SoftWear pad	BAHA Connect System, Dermalock Connect	BoneBridge Bone Conduction Implant (BCI) 601, 602	Cochlear OSI200 and BI300 implant	BHX Implant
Related accessories	Cochlear Mini Mic 2+, Cochlear Phone Clip, Cochlear TV connector	Cochlear Mini Mic 2+, Cochlear Phone Clip, Cochlear TV connector	Charger	Cochlear Mini Mic 2+, Cochlear Phone Clip, Cochlear TV connector, Water wear	Oticon Connect Clip

¹ [510\(k\) Premarket Notification Summary](#)

² [510\(k\) Premarket Notification Summary](#)

³ [510\(k\) Premarket Notification Summary](#)

⁴ [510\(k\) Premarket Notification Summary](#)

⁵ [510\(k\) Premarket Notification Summary](#)

⁶ [510\(k\) Premarket Notification Summary](#)

⁷ [510\(k\) Premarket Notification Summary](#)