

**K081011 AREX SCRU 2 HEADLESS COMPRESSION SCREWS,  
 MODELS: P2P10, P2P15, P2P20, P2P25, P2P30, P2P35, P2P40,  
 P2P45**

Nov 7, 2008  
 212 days to decision

K081011 · Product code: **HWC** · Orthopedic  
 Source: <https://www.510kdatabase.net/k081011/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Apr 9, 2008
Decision date	Nov 7, 2008
Days to decision	212 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Arex USA</b>
Location	Collegeville, PA, US
Contact	ELLEN HOKANSON
510(k) history	2 submissions · 2 cleared · 2008-2010

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k081011/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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