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Premarket Approval (PMA)



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Note: this medical device record is a supplement. The device description may have changed. Be sure to look at the [original PMA](#)²² to get an up-to-date view of this device.

Trade Name BAK INTERBODY FUSION SYSTEM
Classification Name [Intervertebral Fusion Device With Bone Graft, Lumbar](#)²³
Generic Name Lumbar Interbody Fusion Instrumentation
Regulation Number [888.3080](#)²⁴
Applicant SPINE-TECH, INC.
PMA Number P950002
Supplement Number S002
Date Received 02/05/1997
Decision Date 05/09/1997
Product Code MAX [[Registered Establishments With MAX](#)²⁵]
Advisory Committee Orthopedic
Supplement Type Real-time Process
Supplement Reason Change Design/components/specifications - Other
Expedited Review Granted? No

Combination Product No

Approval Order Statement

Approval of the addition of the following sizes to the bak product line: a) bak implants (minor diameter (mm) x length (mm)) 11x20, 11x24, 11x28, 11x32, 11x36; 13x24, 13x28, 13x32, 13x36, 13x40; 15x28, 15x32, 15x36, 15x40, 15x44; 17x20, 17x32, 17x36, 17x40, 17x44; 19x24, 19x28, 19x32, 19x36, 19x40, 19x44; 21x28, 21x32, 21x36, 21x40, 21x44; and (b) end caps (diameter (mm)) 11; 19; and 21.

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Page Last Updated: 07/28/2014

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