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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Silver Spring, MD 20993
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