Urgent Safety Communication

Urgent Recall of AMENDIA Omega Lumbar Interbody Fusion Device Manufactured by Spinal Elements

Device/ Product Name:	**AMENDIA Omega Lumbar Interbody Fusion Device**
Lot numbers/Serials:	Part Number 72-00-2-092812-11 Lot Number 140760
Manufacturer:	Spinal Elements (Previously AMENDIA)
Problem:	Saudi FDA would like to bring your attention to the published Recall about **AMENDIA Omega Lumbar Interbody Fusion Device** Manufactured by **Spinal Elements** that Omega LIF interbody implants labeled as having 11 degrees of lordosis was assembled using components manufactured with 4 degrees of lordosis.
Recommendation/Actions:	The manufacturer requested return of the product. Distributors who further distributed the product were directed to notify their customers.
Devices/Products photo:	

Authorized Representative Details	**Company name:**	**There is no AR**
	Contact Person:	**NA**
	Phone:	**NA**
	Email:	**NA**

For further information, please **see the Recall below or Click Here.**

If you have the product mentioned above inform NCMDR Team immediately.

Healthcare Professionals should **report** any adverse events suspected to be associated with affected devices above (or other Medical Devices) to:

National Center for Medical Devices Reporting.
Medical Devices Sector
Saudi Food and Drug Authority
Postal Address: Saudi Arabia - Saudi Food and Drug Authority (3292)
North Ring Road - Al Nafal Unit (1)
Riyadh 13312 - 6288
Tel: +966 (11) 2038222 Ext: 2406, 2412
Fax: +966 (11) 2757245

For latest published Recalls/Alerts, please visit (NCMDR Website)

Sincerely,
NCMDR Team

U.S FDA Recall

Reference Number: mdprc 116 05 18 000

Date submitted: 09/09/39

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Manufacturer:	Spinal Elements
Device Type:	AMENDIA Omega Lumbar Interbody Fusion Device
Description:	Intervertebral fusion device with bone graft, lumbar
Medical Device Identifier:	AMENDIA Omega Lumbar Interbody Fusion Device, Part Number 72-00-2-092812-11 Lot Number 140760
Reason of Field Safety Corrective Action:	Omega LIF interbody implants labeled as having 11 degrees of lordosis was assembled using components manufactured with 4 degrees of lordosis.
Remedy Action:	The firm requested return of the product. Distributors who further distributed the product were directed to notify their customers.
Athorized Representative/Importer/Distributor:	N/A
Report Source:	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=163816
Source Ref. Number:	Z-1912-2018
SFDA Comments:	SFDA urges all hospitals that have devices subjected to recall, to contact the company.
Attachments:	No Attachments

View History