



Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Aomori Olympus Co. Recalls Olympus Distal Attachments For Exceeded Di-2-Ethylhexyl Phthalate Levels

Recall Date	Product Description	Recalling Firm	Recall Reason
9/13/2023	Olympus Distal Attachment (In Olympus Disposable Emr Kit) Designed to be attached to the distal end of the endoscope. Disposable EMR Kit: K-001, K-002, K-003, K-004, K-011, K-012	AOMORI OLYMPUS CO., LTD. Kuroishi, Japan	The Distal Attachment contain di-2-ethylhexyl phthalate (DEHP), which exceeds the permissible exposure level calculated according to ISO 10993-17: 2002
9/13/2023	Reusable Distal Attachments Models: MH-462, MH-463, MH-464, MH-465, MH-466, MH-483, MH-587, MH-588(US), MH-589, MH-590, MH-591, MH-592, MH-593, MH-594, MH-595, MH-596, MH-597, MH-598, MAJ-289, MAJ-290, MAJ-291, MAJ-292, MAJ-293, MAJ-294, MAJ-295, MAJ-296, MAJ-297, MAJ-663, MAJ-664, MAJ-665, MAJ-666	AOMORI OLYMPUS CO., LTD. Kuroishi, Japan	The Distal Attachment contain di-2-ethylhexyl phthalate (DEHP), which exceeds the permissible exposure level calculated according to ISO 10993-17: 2002

Recall Class	Product Identification	Distribution	Affected Dates
II	Olympus Distal Attachment (In Olympus Disposable Emr Kit) (1)K-001: Lot Numbers: 5835330 0XI, 0YI, 12I, 14I, 15I, 16I, 17I, 26K, 27K, 28K, 29K, 2XK, 2YK, 2ZK, 31K, 32K. UDI: 4953170048562 (2) K-002 Lot Numbers: 5835430 0XI, 0YI,	1048 Units Nationwide including California	27 July 2023, and prior

	<p>12I, 13I, 14I, 16I, 17I, 27K, 2XK, 2YK, 2ZK 4953170048579 K-003 5835530 0XI, 0YI, 12I, 13I, 14I, 15I, 16I, 17I, 25K, 26K, 27K, 28K, 29K, 2XK, 2YK, 2ZK UDI:4953170048586 (3)K-004 Lot Numbers: 5835630 16I, 17I, 26K UDI: 4953170048593 (4)K-011 Lot Numbers: N2485230 0XI, 15I, 17I UDI: 4953170214035 (5) K-012 Lot Numbers: N2485330 16I, 17I UDI: 4953170214042</p>		
II	<p>Reusable Distal Attachments Model: UDI: MH-462 4953170047732 MH-463 4953170047756 MH-464 4953170047770 MH-465 4953170047794 MH-466 4953170047817 MH-483 N/A MH-587 4953170047855 MH-588 4953170364518 (US) ...</p>	1252 Units Nationwide including California	27 July 2023, and prior

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CDPH Food and Drug Branch
MS 7602 ● P.O. Box 997435 ● Sacramento, CA 95899-7435
(916) 650-6500 ● (916) 650-6650 FAX
Internet Address: www.cdph.ca.gov

