FDA

See Related Information[22]

Class 2 Device Recall Arkon Anesthesia Delivery System, Model 99999.

Date Initiated by Firm	February 08, 2017
Create Date	March 14, 2017
Recall Status[1]	Open[3], Classified
Recall Number	Z-1460-2017
Recall Event ID	76429[23]
510(K)Number	K113051[24]
Product Classification	Ventilator, continuous, facility use[25] - **Product Code** CBK[26]
Product	Arkon Anesthesia Delivery System, Model 99999. Product Usage: Continuous Ventilator The Arkon Anesthesia Delivery System is designed to provide emergency oxygen, vaporized agent delivery and manual ventilation in the event of a power failure scenario. Clinicians are able to use Emergency O2 and manually ventilate the patient, providing gas and agent. However, the anesthesiologist will not have access to mechanical ventilation or ventilator monitoring.
Code Information	US Serial numbers: ARKN-000003, ARKN-000004, ARKN-000011, ARKN-000012, ARKN-000013, ARKN-000014, ARKN-000016, ARKN-000017, ARKN-000019, ARKN-000020, ARKN-000021, ARKN-000022, ARKN-000023, ARKN-000024, ARKN-000025, ARKN-000026, ARKN-000027, ARKN-000028, ARKN-000029, ARKN-000030, ARKN-000031, ARKN-000037, ARKN-000038, ARKN-000039, ARKN-000040, ARKN-000041, ARKN-000042, ARKN-000044, ARKN-000045, ARKN-000046, ARKN-000047, ARKN-000048, ARKN-000049, ARKN-000051, ARKN-000054, ARKN-000055, ARKN-000056, ARKN-000057, ARKN-000058, ARKN-000059, ARKN-000060, ARKN-000061, ARKN-000062, ARKN-000063, ARKN-000064, ARKN-000065, ARKN-000066, ARKN-000067, ARKN-000068, ARKN-000069, ARKN-000070, ARKN-000071, ARKN-000072, ARKN-000073, ARKN-000074, ARKN-000075, ARKN-000076, ARKN-000077, ARKN-000078, ARKN-000082, ARKN-000091, ARKN-000092, ARKN-000093, ARKN-000094, ARKN-000095, ARKN-000096, ARKN-000097, ARKN-000098, ARKN-000099, ARKN-000100, ARKN-000101, ARKN-000102, ARKN-000103, ARKN-000104, ARKN-000105, ARKN-000106, ARKN-000107, ARKN-000108, ARKN-000109, ARKN-000110, ARKN-000111, ARKN-000112, ARKN-000113, ARKN-000114, ARKN-000115, ARKN-000116, ARKN-000117, ARKN-000119, ARKN-000120, ARKN-000123, ARKN-000129, ARKN-000130, ARKN-000132, ARKN-000133, ARKN-000134, ARKN-000135, ARKN-000136, ARKN-000137, ARKN-000138, ARKN-000139, ARKN-000140, ARKN-000141, ARKN-000142, ARKN-000143, ARKN-000144, ARKN-000145, ARKN-000149, ARKN-000150, ARKN-000151, ARKN-000152, ARKN-000153, ARKN-000154, ARKN-000155, ARKN-000157, ARKN-000167, ARKN-000168, arkn-000169, arkn-000170, ARKN-000171, arkn-000173, arkn-000174, arkn-000175, arkn-000176, arkn-000177, arkn-000178, arkn-000179, arkn-000180, arkn-000181, arkn-000182, arkn-000183, arkn-000184, arkn-000185, ARKN-000186, ARKN-000187, ARKN-000188, ARKN-000189, ARKN-000190, ARKN-000191, ARKN-000192, ARKN-000193, ARKN-000194, ARKN-000196, ARKN-000197, ARKN-000198, ARKN-000199, ARKN-000200, ARKN-000201, ARKN-000202, ARKN-000203, ARKN-000204, ARKN-000205, ARKN-000206, ARKN-000207, ARKN-000208, ARKN-000209, ARKN-000210,

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Recalling Firm/ Manufacturer	Del Mar Reynolds Medical, Ltd. 1 2 Harforde Court John Tate Road Business Park Hertford United Kingdom
For Additional Information Contact	Technical Support 425-363-5212
Manufacturer Reason for Recall	Spacelabs has received reports of the Arkon Anesthesia Delivery System, Model 99999, shutting down without warning. The power supply has failed in a way that does not trigger the normal on battery alarms.
FDA Determined Cause [2]	Software design
Action	On 08 February 2017, a customer letter will be sent via priority service, return receipt requested, to all U.S. customers. Records of notification will be maintained to ensure complete notification. On 15 February 2017, a customer letter (translated as necessary) will be emailed to all international subsidiaries and distributors of record. Records of notification will be maintained to ensure complete notification. Upgrade is expected to be available in April 2017; all affected Arkon Anesthesia Delivery Systems will receive a software upgrade onsite.
Quantity in Commerce	325 devices sold to 35 US consignees and 76 devices sold to 14 international consignees
Distribution	Worldwide Distribution - US nationwide and internationally in the following countries: BOLIVIA, CANADA, CHINA, ECUADOR, FRANCE, IRELAND, MALAYSIA, MEXICO, MOROCCO, NETHERLANDS, PANAMA, PERU, POLAND, UNITED KINGDOM.
Total Product Life Cycle	TPLC Device Report[27]

[1] A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about medical device recalls[28].
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.
[3] The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.

510(K) Database 510(K)s with Product Code = CBK and Original Applicant = SPACELABS HEALTHCARE[29]

Links on this page: