



Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Hamilton Medical Recalls Hamilton C6 Ventilator for Software Error

| Recall Date | Product Description | Recalling Firm | Recall Reason |
|-------------|-----------------------------------|-------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 5/3/2023 | Hamilton-C6 REF: 160021 | HAMILTON MEDICAL AG Bonaduz, Switzerland | Software error causes, safety ventilation malfunction, in which ventilation continues in the "safety ventilation" mode with audible/visible alarm - patient inputs are not monitored, if the following coincide 1) A mode change to an adaptive mode (ASV, APVcmv, APVsimv, INTELLiVENT-ASV, (S)CMV+, SIMV+), and 2) The controller and/or humidifier is connected to the ventilator and is operational. |

| Recall Class | Product Identification | Distribution | Affected Dates |
|--------------|-------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|-------------------------|
| II | Hamilton-C6 9463, 9329, 9243, 9337, 9236, 9230, 9235, 9353, 9535, 9579, 9575, 9578, 9508, 9576, 9582, 9553, 9590, 9543, 9577 | 19 Units in California | May 2022 - July 2022 |

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