California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Noah Medical Galaxy System and bronchoscope

Recall Date	Product Description	Recalling Firm	Recall Reason
12/20/2024	Galaxy System (GAL-001) Intended to provide bronchoscopic visualization of and access to patient airways for diagnostic and therapeutic procedures.	Noah Medical	Bronchoscopic visualization system power supplies have defective semiconductor components that may fail unexpectedly, which could result in an aborted procedure since it is a non recoverable failure. Manual removal of the bronchoscope when the system is not functioning can increase the chance of injury to the tissues of the lung as the scope is withdrawn including the possibility of pneumothorax.
12/12/2024	Galaxy bronchoscope (Product GALB-001) used with Instructions for use, Part: 10000752, part of the Noah Medical Galaxy System (GAL-001)		Not all biopsy tools meant to fit bronchoscope channel (2.1mm inner diameter/length greater or equal to 1100mm) will pass through if scope channel positioned in

			sharp bend (approx. greater than 100-deg.), excessive force may result in tissue injury/pneumothorax; instruments with long rigid distal sections may exhibit insertion resistance when bronchoscope bending section significantly articulated.

Recall Class	Product Identification	Distribution	Affected Dates
II	UDI-DI: 00850048825048 Serial Numbers: CRB-1502 - CRB-1532 UDI-DI: 00850048825048 IFU Revision: J and all prior versions All bronchoscope lots used with the following system serial numbers: CRB-1502 - CRB1554	4 units in California	October and prior

For additional information, please visit: FDA Website (GAL-001) and FDA Website (GALB-001).