California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Abiomed, Inc. Recalls Automated Impella Controller (AIC)

Recall Date	Product Description	Recalling Firm	Recall Reason
7/26/25	Automated Impella Controller (AIC), used in left heart support blood pump, including the following: 1. Impella Controller, Packaged, AU; Product Code: 0042-0000-AU. 2. Impella Controller, Packaged, CA; Product Code: 0042-0000-CA. 3. Impella Controller, Packaged, EU; Product Code: 0042-0000-EU. 4. Impella Controller, Packaged, EU, Loaner; Product Code: 0042-0000-EU-L. 5. Impella Controller, Packaged, IN; Product Code: 0042-0000-IN. 6. Impella Controller, Packaged, JP; Product Code: 0042-0000-JP. 7. Impella Controller, Japan, Loaner; Product Code: 0042-0000-JP-L. 8. Impella Controller, Packaged, UK; Product Code: 0042-0000-UK. 9. Impella Controller, UK, Loaner; Product Code: 0042-0000-UK-L. 10. Impella Controller, Packaged, US; Product Code: 0042-0000-US. 11. Impella Controller, Packaged, US, Loaner; Product Code: 0042-0000-US-L. 12. Impella Optical Controller, Packaged, AU; Product Code: 0042-0010-AU. 13. Impella Optical Controller, Packaged, EU;	Abiomed, Inc.	A potential issue with the Automated Impella Controller (AIC) not detecting an Impella pump when it is connected

	Product Code: 0042-0010-EU. 14. Impella Optical Controller, EU, Loaner; Product Code: 0042-0010-EU-L. 15. Impella Optical Controller, Packaged, IN; Product Code: 0042-0010-IN. 16. Impella Optical Controller, Packaged, UK; Product Code: 0042-0010-UK. 17. Impella Optical Controller, UK, Loaner; Product Code: 0042-0010-UK-L. 18. Impella Optical Controller, Packaged, US; Product Code: 0042-0010-US. 19. Impella Optical Controller, US, Loaner; Product Code: 0042-0010-US-L. 20. Optical, AIC, Impella Connect, Packaged, AU; Product Code: 0042-0040-AU. 21. Optical AIC w/Impella Connect, Packaged, CA; Product Code: 0042-0040-CA. 22. AIC w/Remote Link, Packaged, Cln Trl, US; Product Code: 0042-0040-CT-L. 23. Optical AIC w/Impella Connect, Packaged, EU; Product Code: 0042-0040-EU. 24. Optical AIC w/Impella Connect, EU, Loaner; Product Code: 0042-0040-EU-L. 25. Optical AIC w/Impella Connect, Pkgd, JP; Product Code: 0042-0040-JP. 26. Optical AIC w/Impella Connect, Pkgd, JP; Product Code: 0042-0040-JP-L. 27. Optical, AIC, Impella Connect, Pkgd, UK; Product Code: 0042-0040-UK. 28. Optical, AIC, Impella Connect, Pkgd, US; Product Code: 0042-0040-US. 29. Optical AIC Impella Connect, US, Loaner; Product Code: 0042-0040-US-L. 30. Dbl optical, AIC Impella Connect, Phg US; Product Code: 1000201. 31. AIC w/Impella Connect for ECP; Product Code: 1000432.		

Confidential - Low

Recall Class	Product Identification	Distribution	Affected Dates
I	Product code information	Worldwide distribution. US Nationwide, Australia, Austria, Belgium, Brunei Darussalam, Canada, Colombia, Croatia, Czechia, Denmark, Finland, France, Germany, Greece, Hong Kong, India, Ireland, Israel, Italy, Japan, Kuwait, Luxembourg, Malaysia, Mexico, Netherlands, Norway, Pakistan, Panama, Poland, Saudi Arabia, Serbia, Singapore, Slovenia, Spain, Sweden, Switzerland, Taiwan, Thailand, United Arab Emirates, and United Kingdom.	June 2025 and prior.

For additional information, please visit the FDA Website

Confidential - Low