



Food and Drug Branch – Device Recalls

**CALIFORNIA DEVICE RECALL INFORMATION SHEET**

**Abbott Medical Recalls DragonFly OpStar Imaging Catheter for Potential Loose Catheter Marker Band That May Cause Patient Harm**

| Recall Date | Product Description   | Recalling Firm                                 | Recall Reason  |
|-------------|---|--|--|
| 3/30/2022   | <b>Dragonfly OpStar Imaging Catheter</b><br>REF 1014651/1014652,<br>0.068 in, 0.014 in, 135 cm,<br>STERILE EO | <b>Abbott Vascular</b><br>Temecula, California | There is a potential that the proximal marker may separate from the imaging catheter |

| Recall Class | Product Identification   | Distribution                                    | Affected Dates       |
|--------------|--|---|----------------------|
| I            | All lots distributed to end users without valid CLIA ID UPC: 8 806121 763044 | 14,544 UNITS<br>Nationwide including California | March 2022 and prior |

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE [FDA WEBSITE](#)

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](http://www.cdph.ca.gov)

