

## **Data Sharing Statement**

### **Data**

**Data available:** No

### **Additional Information**

**Explanation for why data not available:** In this cross-sectional study, all 510(k) devices subject to Class I recalls between January 2017 through December 2021 (“index devices”) were identified from the FDA’s annual recall listings. Information about predicate devices was extracted from the Devices@FDA database for anyone needing availability.