FDA 510(k) Premarket Notification

K233170 cryoICE cryoSPHERE+ Cryoablation Probe (CRYOSP)

CLEARED

Oct 26, 2023
29 days to decision

K233170 · Product code: **GXH** · Neurology
Source: https://www.510kdatabase.net/k233170/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Device, Surgical, Cryogenic (GXH)
Date received	Sep 27, 2023
Decision date	Oct 26, 2023
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	cryoICE cryoSPHERE+ Cryoablation Probe (CRYOSP-L); cryoICE cryoSPHERE MAX Cryoablation Probe (CRYOSMAX); cryoICE cryoSPHERE MAX Cryoablation Probe (CRYOSMAX-L)

APPLICANT

Company	**AtriCure, Inc.**
Location	West Chester, OH, US
Contact	Erica Schwab
Website	http://www.atricure.com/
510(k) history	59 submissions · 59 cleared · 2001-2025

AtriCure, Inc. specializes in surgical devices for atrial fibrillation treatment and pain management. The company develops ablation systems, left atrial appendage exclusion devices, and minimally invasive surgical instruments. AtriCure operates with a manufacturing facility in West Chester, Ohio, and serves healthcare professionals globally. AtriCure has received FDA 510(k) clearances from total submissions since 2001. The company focuses primarily on cardiovascular devices, including surgical ablation systems, LAA management solutions, and epicardial access tools. The la...