CLEARED

K191060 ACIST CVI1 Contrast Delivery System, A1000 Syringe Kit, A1000V Syringe Kit, BT2000 Manifold Kit, BT2000 Manifold Kit, AngioToiuch Hand Controller Kit

Jul 18, 2019
87 days to decision

K191060 · Product code: **DXT** · General Hospital
Source: https://www.510kdatabase.net/k191060/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Injector And Syringe, Angiographic (DXT)
Date received	Apr 22, 2019
Decision date	Jul 18, 2019
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Acist Medical Systems, Inc.**
Location	Eden Prairie, MN, US
Contact	Matthew D. Stepanek
510(k) history	14 submissions · 14 cleared · 2001-2024