K233959

510(k) Summary

Applicant Information

Manufacturer: AtriCure, Inc.
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Device Information

Proprietary Name: EPi-Ease™ Epicardial Access System (EAS)

Common Name: EPi-Ease

Classification: Introducer, Catheter
Regulatory Class: Class II; per 21 CFR 870.1340
Product Code: DYB
Classification Panel: Cardiovascular

Predicate Device: Agilis PF Introducer System
(K111943, September 29, 2011)

Device Description

EPi-Ease is composed of a radiopaque blunt dissection distal tip, a distal suction port designed to draw pericardial tissue into the device, a hollow 22-gauge Tuohy needle that enables puncture of the pericardium internal to the device, and a lumen to allow for insertion of an endoscope to provide direct visualization during blunt dissection, needle puncture, and guidewire delivery. The distal suction port connects to the device handle and terminates in a standard luer connection. The needle connects to the handle and terminates in a needle actuator, which enables extension, retraction, and rotation of the encased needle a limited distance within the distal tip and provides a port for insertion of a commercially available guidewire. After puncture, the device allows passage of a standard, commercially available .014” guidewire. An additional flushing port is available using the 3-way stopcock.

Intended Use / Indications for Use

The EPi-Ease™ Epicardial Access System is intended to access the epicardial surface of the heart via a subxiphoid approach.

Comparison of Technological Characteristics

- The devices include an equivalent intended use, and;
- No changes were made in operating principle, and;
- The results of the verification and validation testing:
  - Demonstrated equivalency in performance
  - Did not raise any new issues of safety

	Feature	**Predicate:** **Agilis Epicardial Access System**	**Proposed:** **AtriCure EPi-Ease System**
1	Access	Sub-xiphoid	Sub-xiphoid
2	Needle size and Device Profile	17 ga. Tuohy Needle 18 Fr. Device Profile	22 ga. Tuohy Needle 13 Fr. Device Profile
3	Visualization	Fluoroscopy required No endoscopic visualization	Fluoroscopy required Endoscopic visualization
4	Indication for Use	The Epicardial Access System is intended to access the epicardial surface of the heart via a subxiphoid approach to facilitate electrophysiology studies	The EPi-Ease™ Epicardial Access System is intended to access the epicardial surface of the heart via subxiphoid approach
5	Vacuum	N/A	Vacuum-enabled retraction
6	Radiopaque marker	Yes—distal tip	Yes—distal tip
7	Operating Principles	Advancement through adipose tissue to reach pericardial sac, needle punctures pericardial sac, guidewire advances through needle into pericardial sac, introducer advances over guidewire and pre- dilates pericardial sac, sheath advances over guidewire into pericardial sac to access epicardial surface of the heart.	Equivalent. EPi-Ease adds direct visualization, vacuum, and needle advancement limits to mitigate risks associated with the predicate

Performance Data

The following bench testing was conducted for design and performance elements deemed appropriate to demonstrate substantial equivalence to the previously cleared Agilis Introducer. The EPi-Ease device met the predetermined acceptance criteria ensuring substantial equivalence to the predicate. No new safety or effectiveness issues were raised during testing.

Non-clinical Bench Testing:

Test Description	Results
Mechanical Testing: Endoscope testing, guidewire compatibility, structural integrity	PASS
Biocompatibility Testing per ISO 10993-1	PASS
Shelf-Life Testing ASTM F1980-16	PASS
Transit Testing per ISTA 3A	PASS
Sterilization per ISO 11137	PASS
Synthetic Model (CADet) testing	PASS

Conclusion

AtriCure has demonstrated that the EPi-Ease Epicardial Access Device is substantially equivalent in fundamental design, technology, function, device materials, packaging, sterilization, operating principal, and intended use/ indication for use to the predicate device, the Agilis PF Introducer System.