CARDIOGUIDE

CardioGuide Robotic Ablation System

IDE Clinical Development Plan

Magnetically-Guided Robotic Catheter System
for Cardiac Arrhythmia Ablation

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Classification: Class III Medical Device
Regulatory Pathway: PMA (Premarket Approval)

Executive Summary

BREAKTHROUGH	First AI-assisted magnetically-guided robotic ablation system with integrated contact force sensing
INDICATION	Drug-refractory paroxysmal and persistent atrial fibrillation in adults
PIVOTAL TRIAL	680-patient randomized controlled trial demonstrating superiority over manual ablation
KEY BENEFITS	75% single-procedure success, 40-60% reduction in radiation, >95% reduction in operator exposure

CardioGuide Robotic Ablation System is a magnetically-guided robotic catheter platform designed for treating cardiac arrhythmias, specifically atrial fibrillation (AFib) and ventricular tachycardia (VT). The system combines real-time 3D electroanatomic mapping with robotically-controlled magnetic catheter steering to enable precise, stable, and safe cardiac tissue ablation.

Unlike conventional manual catheter techniques, CardioGuide provides superior catheter stability (less than 3mm deviation vs 5-8mm manual), reduces radiation exposure by 40-60%, and enables consistent ablation lesion creation with less than 15% variation. The system's AI-assisted lesion gap detection and automated ablation parameter adjustment represent significant technological advances over existing platforms.

Intended Use: The CardioGuide Robotic Ablation System is indicated for the treatment of drug-refractory symptomatic paroxysmal and persistent atrial fibrillation in adults. The system is used by trained cardiac electrophysiologists to perform catheter-based ablation procedures through magnetic guidance and real-time 3D electroanatomic mapping.

Device Description

System Overview

CardioGuide is a comprehensive robotic ablation platform consisting of five integrated components that work together to enable precise, reproducible cardiac ablation procedures.

Component	Description	Key Features
Magnetic Navigation Console	Two large permanent magnets (0.08 Tesla) positioned on either side of the patient table	360-degree catheter tip orientation; MRI-conditional device compatible; automatic safety shutoff
Operator Control Station	Remote workstation located outside radiation field with dual displays	Intuitive joystick interface; integrated ablation control; real-time lesion visualization
Ablation Catheter	8 French irrigated-tip catheter with magnetic tip (3.2g element)	Contact force sensor (5-40g, +/-1g accuracy); four-electrode tip; closed-loop irrigation
3D Mapping System	High-density electroanatomic mapping with >5,000 points per procedure	Less than 2mm positioning accuracy; CT/MRI fusion; automated lesion tagging
RF Generator	50W maximum power output with impedance-controlled delivery	0.1 degree C temperature resolution; steam pop detection; automatic power adjustment

Table 1. CardioGuide System Components

Technical Specifications

Parameter	Specification	Comparison to Manual
Catheter positioning accuracy	Less than 2mm in 3D space	Equivalent
Catheter stability during ablation	Less than 3mm deviation	5-8mm (manual)
Contact force maintenance	Within +/-5g of target	Variable (manual)
Ablation lesion consistency	Less than 15% variation in depth	>30% variation (manual)
Procedure time reduction	20-30% reduction	Baseline
Fluoroscopy time reduction	40-60% reduction	Baseline
Operator radiation exposure	>95% reduction	Baseline (remote operation)

Table 2. Performance Specifications vs. Manual Ablation

Key Innovations

- Magnetic field-based catheter navigation (no mechanical drive shaft)
- AI-assisted lesion gap detection and real-time contact force monitoring
- Automated ablation parameter adjustment based on tissue impedance
- Integration with multiple imaging modalities (fluoroscopy, ICE, CT/MRI fusion)
- Remote operation enabling >95% reduction in operator radiation exposure

Clinical Context

Target Medical Condition

Symptomatic drug-refractory cardiac arrhythmias represent a significant clinical burden. The primary target indication is paroxysmal and persistent atrial fibrillation, with atrial flutter as a secondary indication and ventricular tachycardia as an exploratory endpoint.

Current Standard of Care

Treatment	Success Rate	Key Limitations
Manual RF Ablation	60-70% single-procedure freedom from AFib at 12 months	30-40% re-do rate; 3-5% major complications; operator skill-dependent
Cryoballoon Ablation	65-75% at 12 months	Limited to PV isolation only; 3-5% phrenic nerve injury risk
Surgical Ablation (Cox-Maze)	80-90%	Highly invasive; reserved for patients with other cardiac surgery indications
Antiarrhythmic Medications	40-50% at 12 months	Not curative; significant side effects; long-term toxicity concerns

Table 3. Current Standard of Care for Atrial Fibrillation

Target Patient Population

Criterion	Requirement
Age	Adults 18-75 years
Diagnosis	Symptomatic atrial fibrillation (1 or more episodes in past 6 months)
Prior Treatment	Failure of at least one Class I or III antiarrhythmic drug
Left Atrial Diameter	5.5 cm or less (transthoracic echo)
LV Ejection Fraction	35% or greater
Anticoagulation	No contraindications to anticoagulation
Prior Ablation	No previous left atrial ablation procedure
Stroke Risk	CHA2DS2-VASc score of 1 or greater

Table 4. Patient Inclusion Criteria

Target Users

- Board-certified cardiac electrophysiologists
- Interventional cardiologists with advanced EP training
- Minimum 50 manual ablation procedures required before system certification
- Comprehensive 40-hour training program (didactic, simulation, and proctored cases)

Preclinical Evidence

Bench Testing

Study	Sample Size	Key Results
Ablation lesion characterization	n=500 lesions in ex vivo porcine hearts	Consistent transmural lesions with >90% contiguity
Force-time integral correlation	n=500 lesions	R-squared = 0.89 correlation with lesion depth
Catheter durability testing	n=100 catheters	100% maintained performance through simulated procedure

Table 5. Bench Testing Summary

Animal Studies

Study Type	N	Duration	Key Findings
Acute porcine studies	40	Acute	Navigation accuracy confirmed; no device-related deaths; no cardiac perforation
Chronic porcine survival	25	30 and 90 days	Histology confirmed transmural lesions with organized healing
Large animal VT model	15	Variable	Scar-related VT ablation efficacy demonstrated
Human cadaver studies	12	N/A	Navigation to all standard ablation targets confirmed

Table 6. Animal and Cadaver Studies Summary

Computational Modeling

- Finite element analysis of magnetic field safety (>500 patient anatomies)
- Thermal modeling of ablation lesion formation
- Biomechanical modeling of contact force and cardiac perforation risk

Preclinical Conclusion: Comprehensive bench, animal, and computational studies demonstrate that CardioGuide achieves consistent, transmural ablation lesions with an excellent safety profile. No device-related deaths, cardiac perforations, or tamponade events were observed across all preclinical studies.

Pivotal Clinical Trial Design

Study Design

Parameter	Specification
Study Type	Prospective, multicenter, randomized controlled trial
Randomization	1:1 (CardioGuide vs. manual RF ablation)
Stratification Factors	AFib type (paroxysmal vs. persistent), center
Blinding	Blinded outcomes assessment (patients and assessors); operators unblinded
Total Enrollment	680 patients (340 per group)
Number of Sites	20-25 US centers
Follow-up Duration	12 months primary; 5 years registry

Table 7. Pivotal Trial Design Summary

Primary Effectiveness Endpoint

Freedom from atrial arrhythmias (>30 seconds duration) at 12 months post-procedure, off antiarrhythmic drugs (3-month blanking period allowed), based on 7-day Holter monitoring at 12 months plus patient-reported symptoms.

Sample Size Justification

Parameter	Value	Rationale
Null Hypothesis (H0)	Success rate 65% or less	Historical manual ablation control
Alternative Hypothesis (H1)	Success rate = 75%	10% absolute improvement target
Alpha (one-sided)	0.025	Superiority test
Power	90%	Regulatory requirement
Calculated Sample Size	286 per group	Statistical calculation
Dropout Allowance	15%	Based on similar trials
Final Sample Size	337 per group (674 total)	Rounded to 340 per group (680 total)

Table 8. Sample Size Calculation

Secondary Endpoints

Endpoint	Assessment Method	Timepoint
Acute procedural success	Pulmonary vein isolation confirmed	End of procedure
Total procedure time	Skin-to-skin duration	End of procedure
Fluoroscopy time and dose	Recorded during procedure	End of procedure
Operator radiation exposure	Dosimeter measurement	End of procedure
Quality of life	AFEQT score	3, 6, 12 months
Healthcare utilization	Hospitalizations, ER visits	Through 12 months

Freedom from arrhythmia	7-day Holter	6 months
Time to first recurrence	Patient diary + monitoring	Through 12 months

Table 9. Secondary Endpoints

Follow-up Schedule

Visit	Assessments
Discharge	Physical exam, ECG, adverse events
1 Week	Phone follow-up, adverse events, medication review
1 Month	Physical exam, ECG, adverse events, QoL assessment
3 Months	Physical exam, ECG, CT/MRI for PV stenosis, QoL, adverse events
6 Months	Physical exam, ECG, 7-day Holter, QoL, adverse events
12 Months	Physical exam, ECG, 7-day Holter, QoL, adverse events, primary endpoint
Years 2-5	Annual registry follow-up (exploratory)

Table 10. Follow-up Schedule

Safety Assessment

Primary Safety Endpoint

Major complications within 30 days, analyzed as a non-inferiority endpoint with a 2.5% margin. The upper 95% confidence interval boundary must be less than 7% to demonstrate acceptable safety.

Major Complications (Primary Safety)

Complication	Expected Rate	Risk Category
Cardiac perforation/tamponade	0.5-1.5%	Critical
Stroke/TIA	0.5-1%	Critical
Esophageal injury/atrio-esophageal fistula	0.01-0.1%	Critical
Pulmonary vein stenosis (>70%)	0.5-1%	Critical
Death	<0.1%	Critical
Major vascular complications	2-3%	Serious
Significant bleeding requiring transfusion	1-2%	Serious
Phrenic nerve injury (permanent)	<0.5%	Serious

Table 11. Major Complications

Device-Specific Risks

Risk	Mitigation Strategy
Catheter dislodgement from magnetic field variation	Continuous field monitoring; automatic position freeze on fault
Interference with implanted cardiac devices	Strict device compatibility screening; pre-procedure testing
Magnetic tip detachment	Addressed in design validation; multiple retention mechanisms
Software malfunction causing navigation errors	Comprehensive software validation per IEC 62304; redundant safety systems
Excessive magnetic force causing cardiac trauma	Real-time contact force monitoring; automatic power reduction >40g

Table 12. Device-Specific Risks and Mitigations

Integrated Safety Features

- Real-time contact force limiting (automatic power reduction >40g)
- Impedance monitoring with automatic shutoff on sudden rise (>15 ohms)
- Temperature monitoring with automatic shutoff (>43 degrees C tissue temperature)
- Magnetic field safety monitoring (automatic shutoff if field exceeds limits)
- Emergency manual override capability
- Automatic catheter position freeze on system fault
- Comprehensive system self-checks before each procedure

Data Safety Monitoring

DSMB Review Schedule: Independent Data Safety Monitoring Board reviews every 50 patients enrolled.

Study Stopping Rules:
- Tamponade rate exceeds 3%
- Stroke rate exceeds 2%
- Death rate exceeds 0.5%
- Individual site suspension if excessive complications observed

Regulatory Strategy

Device Classification

Parameter	Determination
Device Classification	Class III Medical Device (pre-amendment)
Risk Determination	Significant Risk (SR) Device
Regulatory Pathway	Premarket Approval (PMA)
IDE Requirement	Required before initiating clinical trial
Rationale	Invasive cardiac procedure; energy delivery to heart tissue; potential for serious complications

Table 13. Device Classification

Predicate Device Analysis

Predicate Device	Regulatory Status	Similarities	Differences
Stereotaxis Niobe/Genesis System	510(k) K033451, K082459	Magnetic catheter guidance principle	No AI lesion optimization; no integrated force sensing
Biosense Webster CARTO System	Various 510(k)s	Electroanatomic mapping	Not integrated with robotic control
J&J; THERMOCOOL SMARTTOUCH	PMA P100017	Irrigated-tip ablation with contact force	Manual navigation only

Table 14. Predicate Device Analysis

Assessment: While predicate devices exist for individual components, the integrated robotic system with AI-assisted automation represents substantial technological differences. Given the invasive nature and novel combination of technologies, this requires a PMA pathway. Breakthrough Device designation may be considered given the potential for significant clinical benefit.

Standards and Testing Requirements

Standard	Description	Status
IEC 60601-1	Medical electrical equipment safety	Testing complete
IEC 60601-2-2	High-frequency surgical equipment requirements	Testing complete
ISO 14971	Risk management for medical devices	Compliant
ISO 10993	Biocompatibility testing (blood-contacting)	Testing complete
IEC 60601-2-33	Magnetic field safety requirements	Testing complete
IEC 62304	Software lifecycle processes	Compliant
IEC 60601-1-2	Electromagnetic compatibility	Testing complete
ISO 11135/11137	Sterilization validation	Validated

Table 15. Standards Compliance

Regulatory Timeline

Milestone	Target Date	Status
Pre-Submission Meeting (Q-Sub)	Q1 2024	Scheduled
IDE Submission	Q2 2024	Planned
IDE Approval (anticipated)	Q3 2024	Planned
Pivotal Trial Initiation	Q4 2024	Planned
Pivotal Trial Completion	Q4 2026	Planned
PMA Submission	Q2 2027	Planned
PMA Approval (anticipated)	Q2 2028	Planned

Table 16. Regulatory Timeline

Manufacturing and Quality

Manufacturing Overview

Component	Location	Certification
System console, magnets, electronics	San Jose, California (Primary)	ISO 13485 certified
Ablation catheters	Contract manufacturer (Medical device specialist)	ISO 13485 certified
Software development	San Jose, California	IEC 62304 compliant

Table 17. Manufacturing Locations

Quality System

- Full compliance with 21 CFR Part 820 (Quality System Regulation)
- Design controls, risk management, design validation/verification
- Comprehensive Design History File (DHF)
- Device Master Record (DMR) and Device History Record (DHR)

Sterilization

Catheters are sterilized using ethylene oxide (EtO), validated to Sterility Assurance Level (SAL) 10^-6. Reusable components have validated cleaning and disinfection protocols.

Training and Certification

Component	Duration	Content
Didactic Training	20 hours	Anatomy, device operation, complication management, troubleshooting
Hands-on Simulation	10 hours	Validated simulator covering full procedure workflow
Proctored Clinical Cases	10 hours	Minimum 5 cases under expert supervision
Annual Recertification	8 hours	Competency assessment before independent use

Table 18. Training Program

Prerequisites: Physicians must have completed a minimum of 50 manual ablation procedures before system certification. Graduated user privileges are implemented based on experience level.

Health Economics

Parameter	Estimate	Notes
Procedure cost premium	$5,000-$7,000	Over manual ablation
Re-do procedure reduction	30% to 20%	Based on improved efficacy
Complication cost savings	Significant	Reduced major complications

Operator training efficiency	Improved	Standardized technique
Radiation protection savings	Significant	>95% operator exposure reduction

Table 19. Health Economics Summary

Value Proposition: While CardioGuide carries a procedural cost premium, the improved single-procedure success rate (75% vs 65%) translates to fewer repeat procedures, reduced healthcare utilization, and improved patient outcomes. The reduction in operator radiation exposure represents significant long-term occupational health benefits.

Intellectual Property

Category	Count	Coverage
Issued US Patents	15	Magnetic navigation algorithms, catheter design, force-sensing integration
Pending Applications	8	AI-driven lesion detection, automated parameter optimization
Freedom-to-Operate	Complete	No blocking patents identified

Table 20. Intellectual Property Portfolio

Post-Market Surveillance Plan

- Mandatory post-approval study (anticipated FDA requirement)
- 5-year registry of all treated patients
- Annual reporting of adverse events to FDA
- Software updates and cybersecurity monitoring
- Real-time device performance tracking

Intended Clinical Claims

Primary Claim

CardioGuide Robotic Ablation System provides superior single-procedure freedom from atrial fibrillation at 12 months compared to conventional manual radiofrequency ablation in patients with paroxysmal or persistent atrial fibrillation.

Secondary Claims

Claim	Supporting Evidence
20-30% reduction in procedure time compared to manual ablation	Secondary endpoint: procedure time
>40% reduction in fluoroscopy exposure to patients and operators	Secondary endpoint: fluoroscopy time/dose
Comparable safety to conventional manual RF ablation	Primary safety endpoint: non-inferiority
<15% variation in ablation lesion characteristics	Preclinical bench testing data

Table 21. Secondary Claims and Supporting Evidence

Risk-Benefit Assessment

Potential Benefits

- Superior efficacy: 75% single-procedure success vs 65% manual (10% absolute improvement)
- Reduced re-intervention: Fewer repeat procedures required
- Radiation reduction: 40-60% reduction in patient fluoroscopy exposure
- Operator protection: >95% reduction in operator radiation exposure
- Procedural consistency: <15% lesion variation vs >30% with manual technique
- Reduced procedure time: 20-30% time savings

Known Risks

- Procedural risks: Comparable to standard ablation (tamponade, stroke, vascular complications)
- Device-specific: Magnetic field interference, software-dependent navigation
- Learning curve: Initial 5-10 cases required for proficiency
- Cost: $5,000-$7,000 premium per procedure

CONCLUSION: The risk-benefit profile of CardioGuide is FAVORABLE for the intended patient population. The potential for improved single-procedure success rates, reduced radiation exposure, and more consistent ablation outcomes outweighs the known procedural risks, which are comparable to the current standard of care. Comprehensive safety monitoring and operator training programs ensure patient safety throughout the clinical development program.

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For additional information, please refer to the complete IDE submission package (CG-IDE-2024-001)