510(k) SUMMARY

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

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Device Name:	Visual-ICE™ MRI Cryoablation System
Device Classification Name: Regulation Number: Product Code:	Cryosurgical unit and accessories 21 CFR 878.4350 GEH
Predicate Devices 510(k):	Visual-ICE Cyroablation System (K113860) SeedNet MRI Cyroablation System (K021261)
Date of Preparation:	September 27, 2017

Device Description:

The Visual-ICE™ MRI Cryoablation System is a mobile system intended for cryoablative tissue destruction using a minimally invasive procedure. The Visual-ICE MRI Cryoablation System has been designed to permit the delivery of cryoablation treatments under visual guidance in an MR environment. The Visual-ICE MRI System is comprised of a Console, Mobile Connection Panel (MCP) and a Junction Box Assembly. The system is computer-controlled with a touch screen user interface that allows the user to control and monitor the procedure. The console is located in the control room, while the Mobile Connection Panel is located in the magnet room. Junction boxes mounted in the two rooms, and connection of the gas and signal lines between the junction boxes occurs via a penetration panel. The Mobile Connection Panel is constructed of non-ferromagnetic materials to allow for placement within the magnet room close to the scanner. The Visual-ICE MRI Cryoablation System was designed for compatibility with Galil Medical's previously cleared IceRod MRI and IceSeed MRI cryoablation needles (K051052).

The table below provides a summary comparison of the submitted device compared to the predicate devices.

Description of Submitted Device: Visual-ICE MRI Cryoablation System	**Comments related to Predicates:** SeedNet MRI and Visual-ICE Cryoablation Systems (K021261,K113860)
Design and Construction	
Console, MCP and Junction Boxes	Similar to predicate; Visual-ICE MRI is comprised of updated components to address more stringent ESD requirements in the 4th edition of Medical Electrical Equipment EMC standard IEC 60601-1-2
Needle ports	Same as predicate
Channel Lock	Same as predicate
User interface	Same as predicate
Performance and Function	
Principles of Operation: Freezing / Thawing	Same as predicate
Needle Compatibility	Same as predicate
Signals between Console and MCP	Similar to predicate; Fiberoptic lines were selected for Visual-ICE MRI to minimize interference as compared to the electrical conductor lines for the legacy SeedNet MRI System

In summary, the submitted Visual-ICE MRI Cryoablation System has the same technology and principle of operation as the predicate devices.

Indications for Use / Intended Use:
The Visual-ICE MRI Cryoablation System is indicated for use as a cryosurgical tool in the fields of general surgery, dermatology, neurology (including cryoanalgesia), thoracic surgery (with the exception of cardiac tissue), ENT, gynecology, oncology, proctology, and urology. This system is designed to destroy tissue (including prostate and kidney tissue, liver metastases, tumors, and skin lesions) by the application of extremely cold temperatures.

The Visual-ICE MRI Cryoablation System has the following specific indications:

- Urology Ablation of prostate tissue in cases of prostate cancer and Benign Prostate Hyperplasia (BPH)
- Oncology Ablation of cancerous or malignant tissue and benign tumors, and palliative intervention
- Dermatology Ablation or freezing of skin cancers and other cutaneous disorders; Destruction of warts or lesions, angiomas, sebaceous hyperplasia, basal cell tumors of the eyelid or canthus area, ulcerated basal cell tumors, dermatofibromas, small hemangiomas, mucocele cysts, multiple warts, plantar warts, actinic and seborrheic keratosis, cavernous hemangiomas, peri-anal condylomata, and palliation of tumors of the skin
- Gynecology Ablation of malignant neoplasia or benign dysplasia of the female genitalia
- General surgery Palliation of tumors of the rectum, anal fissures, pilonidal cysts, and recurrent cancerous lesions, ablation of breast fibroadenomas
- ENT Palliation of tumors of the oral cavity and ablation of leukoplakia of the mouth
- Thoracic surgery (with the exception of cardiac tissue)
- Proctology Ablation of benign or malignant growths of the anus or rectum

The intended use and indications for use are the same as the predicates with the exception that warts, hemorrhoids and ablation of cardiac tissue have been excluded for international indication alignment and marketing reasons. Galil Medical contends that there are no differences to the intended therapeutic, diagnostic, prosthetic, or surgical use of the device, and that the device is safe and effective when used as labelled.

Summary of Performance Data and Substantial Equivalence:
A full battery of verification and validation testing was conducted on the Visual-ICE MRI Cyroablation System to ensure that the design, functionality, and performance met all the specified requirements and that the features of the system satisfy its intended use. Testing was conducted according to protocols based on international standards and in-house requirements. Verification testing included system testing, electrical testing, mechanical testing, packaging and labeling testing, software testing. System testing assessed whether the functional requirements of the system as a whole were satisfied by the design. Mechanical testing evaluated the mechanical robustness of the system and sub-systems, functional testing of the gas system, and tests of mechanical safety requirements. Electrical testing assessed the functional aspects of the circuit assemblies, tests of electromagnetic compatibility and immunity (EMC/EMI), and tests of electrical safety requirements. Software testing exercised individual units of software as well as tests of the functionality of the entire software package. Validation testing included design and usability testing and animal testing. Test results demonstrated that the Visual-ICE MRI Cryoablation System meets defined specifications, is substantially equivalent to the predicate devices, and does not raise any new issues of safety and effectiveness for its intended use.

Conclusion:
The information and data provided in this Traditional 510(k) Premarket Notification establish that the Visual-ICE MRI Cryoablation System is substantially equivalent to the legally marketed predicate devices with regard to performance, safety, and effectiveness for its intended use.