Health Technology Review	
Technology Ref.:	HTA24010
Technology Name/Version/Model:	Edison System/Histotripsy, SW Version 2.1.X
Approvals by International Bodies:	US FDA DEN220087
Company name:	Al Naghi Medical
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Short Description of the Technology:	The EdisonTM System (Edison) is intended for the non-invasive mechanical destruction of liver tumours, including the partial or complete destruction of unresectable liver tumours via histotripsy. This includes any malignancy to the liver from any primary cancer in patients that range from early to late stage in their disease progression, as determined and assessed by the treating physician. Histotripsy's non-invasive, non-thermal and non-ionizing nature creates the potential for patients to receive locoregional treatment that may augment current standard of care chemotherapies and immunotherapies for both primary and secondary liver tumours.

Health Technology Assessment Team Recommendation:	**Approve**

Summary of Review:

HistoSonics is at the forefront of this technological advancement, seeking to expand histotripsy's clinical applications and commercialize the Edison system for liver treatments in the U.S. and internationally. The Edison system represents a significant leap forward in medical technology, offering a novel, safer, and more efficient method for treating tumors.

FDA De Novo clearance has been granted to the Edison system for its application in the non-invasive destruction of liver tumors, highlighting its potential as a pioneering treatment. The approval was supported by data from the HOPE4LIVER trials, which demonstrated high success rates and a low complication rate, reinforcing the system's efficacy and safety.

Advantages	Disadvantages
International bodies approval: US FDA DEN220087	Limited Clinical Data: as a relatively new technology, the long-term effectiveness and potential side effects of histotripsy may not be fully understood
Safety and Efficacy: early trial results and FDA clearance underscore the system's safety and effectiveness in destroying liver tumors	Regulatory Limitations: currently, the Edison system's use in kidney applications is restricted to investigational use by federal law, indicating that full regulatory approvals for broader

	applications are still pending. This limitation affects its immediate availability for various treatments outside liver tumors
Non-Invasiveness: unlike traditional surgeries that require incisions, the Edison system operates externally, reducing the risk of infections and complications associated with open or minimally invasive surgeries.	Accessibility: advanced technologies like the Edison system may be initially available only at specialized centers, potentially limiting patient access
Reduced Recovery Time: patients can expect quicker recovery times due to the non-invasive nature of the procedure	Patient Selection Criteria: not all patients or tumors may be suitable for treatment with the Edison system. Factors such as the size, location, and type of tumor, as well as the patient's overall health and medical history, could affect eligibility and treatment outcomes
Precision and Control: the system allows for precise targeting of tumors without damaging surrounding healthy tissue.	
Preservation of Organ Function: by selectively targeting and destroying tumor cells while sparing surrounding tissue and structures	
Patient Comfort: early experiences suggest that patients undergo the procedure with minimal discomfort and report less pain post-treatment compared to traditional methods,	

We recommend an **approval of using this technology** for Market entry with the following conditions:

1. Approval of Edison System/Histotripsy, SW Version 2.1.X intended to be used for liver tumor.
2. It should be performed by skilled and experienced medical professionals that completed a comprehensive training program.
3. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees.
4. Provision of regular updates and reports about the product to DOH upon request.

Moreover, DOH has the right to stop the product at any stage if deemed necessary, initial conditions and any subsequent conditions must be satisfied before obtaining final approval. Failure to do so will reflect in provoking the approval.

Technology Image


Population, setting and intended user for Technology "Edison System/Histotripsy"

- **Population/ Intended User**;
  - Individuals with Liver Tumors.
  - Liver patients seeking non-invasive treatment options.
  - Individuals with Tumors in Locations Difficult to Treat Surgically
- **To be performed by**:
  - Skilled and experienced medical professionals that completed a comprehensive training program.
- **Clinical Setting:**
  - Hospitals specialized in cancer treatment for the indication.
- **Condition of use:**
  - As per the manufacturer's instructions.
- **Exclusion criteria:**
  - Not suitable for patients who recently received live vaccines.