

# **magAssist Co., Ltd.**

## **Category:**

Best Startup

## **Company Name:**

magAssist Co., Ltd.

## **Turnover and/or Funding:**

Total Funding: around 90 million USD

## **Sub-Category:**

Medical Technology / Digital Health

## **Corporate history (creation, key milestones, main funding,...)Information on Condition / Disease and need for solution / product (prevalence, existing treatments / solutions):**

### **1. Company Overview:**

Mission: Technology for Life- Advancing medical technology through innovation to save more lives.

Vision: Leading multi-organ support from heart failure, empowering life at critical moments

Values□ Patient-centric. Excellence-driven. Purpose-led.

We innovate with compassion and science to serve those in greatest need.

### **2. Leadership:**

1) CEO & Founder: Po-Lin Hsu, PhD

ASAIO Fellow Award (2014); ISMCS Board Member

Dual PhDs, RWTH Aachen & Cambridge

FORTUNE Most Influential Women in China (2021)

15+ years in circulatory support & medical mechatronics

### **3. Major Milestones & Recognitions**

2021: First patient treated with MoyoAssist

2023:

-MoyoAssist: NMPA Innovative Device designation

-NyokAssist™: FDA Breakthrough Device designation & NMPA Innovative Device designation

2024: NyokAssist™ launched clinical trials in China

To date:

-100+ patients supported with MoyoAssist

#### 4. The Unmet Medical Need

##### 1) Heart Failure: A Growing Global Health Concern

-64M+ patients globally

-1~2% adult prevalence in developed nations, increasing with aging and CAD

##### 2) Rising High-Risk Cardiovascular Events and High Mortality Rate

-2M+ annual cases of cardiogenic shock or ADHF (US + China)

-600K PCIs/year in US; 1.5M+ in China

-pVADs are uniquely positioned among other MCS devices as they offer a minimally invasive approach for hemodynamic stabilization of patients with acute heart failure

-High risk factors include □ Advanced age; Multivessel disease; complexity of coronary lesions; Unprotected or distal left main disease; depressed ventricular function;

Concomitant multiorgan involvement, and other non-cardiac issues; While there remains a high mortality rate in surgeries: 2.2% (CHIP 4+), 3.3% (CHIP 5+)

#### 5. Economic Burden

Among the top cost drivers in national healthcare budgets globally, the cost of managing heart failure, including hospitalizations, medications, and long-term care, is substantial and continues to grow

The global burden of heart failure is substantial. The annual cost of caring for a patient with heart failure is nearly \$30,000 in the US. A 2025 publication reported that the total global costs of HF were estimated at \$284.17 billion (\$136.86B direct, \$147.31B indirect)

#### 6. Gaps in Current Treatment Options

- Drug Limitations: Many patients are unresponsive to GDMT

- Implantable VADs & Transplants: Invasive, costly, and not suitable for urgent or bridge-to-decision situations

- Current MCS Technologies: IABP: Minimal support, no survival benefit (confirmed by IABP-SHOCK II trial); ECMO/TandemHeart®: High complication rates, poor fit for PCI use

- High-Risk PCI: Unmet Needs with Current Standard of Care; Market dominated by a launched pVAD, with limited adaptability to diverse anatomies (e.g., smaller Asian vasculature)

#### 7. Strategic Solution

- Focus on an intelligent, modular Platform-based : for the treatment of multi-organ failure.

- Products □

##### 1) NyokAssist™ Interventional VAD:

-9Fr delivery profile, up to 5L/min flow

-Lower incidences of complications: <10FR VS 14FR can reduce the probability of vascular morbidity and bleeding by 3-4 times

## 2) MoyoAssist Extra VAD:

- Full maglev pump, supports up to 30 days
- Short - to mid-term ventricular support for patients with cardiogenic shock, bridge to transplant, and biventricular failure

## 3) BreathMo®

- Shared console with MoyoAssist, which won the IF DESIGN AWARD 2022
- One engine, many functions = low system cost, scalable expansion

# **History of the development of the solution/product (Intellectual Property, preclinical and clinical datas, development collaborations):**

## 1. Scientific Foundation & R&D Philosophy

- Platform Origin: Rooted in 15+ years of research in extracorporeal circulation, blood compatibility, and intelligent control systems
- R&D Principle: Build simple, robust, and intelligent support systems tailored to acute critical care
- Interdisciplinary Integration:  
Mechatronics + Hemorheology + Biocompatibility  
Internal R&D team of 100+ engineers, clinicians, and regulatory experts

## 2. Intellectual Property & Global Regulatory Recognition

- Ever since our founding, we have applied for and/or been granted over 300 patents, covering various applications in the fields of extracorporeal ventricular assist devices, percutaneous ventricular assist devices, ECMO systems, and organ preservation systems. Over 60% of patent filings are invention applications, including international patents under the Patent Cooperation Treaty (PCT).
- Patent Portfolio: Patents covering magnetic levitation solutions, structural device designs, self-expandable mechanisms, novel hemocompatible pump designs, miniaturized interventional delivery systems and multiple methods of operation and system protocols.

## 3. Clinical Evidence-NyokAssist™

- NyokAssist™ has passed bench tests and animal studies, demonstrating the ease of device delivery and withdrawal with a 9Fr insertion sheath, as well as its hydraulic capacity as a pump.
- NyokAssist™ is currently undergoing a prospective, multicenter, randomized controlled clinical trial in China to assess the safety and efficacy of the device in patients with HRPCL. The study enrolled patients with an average left ventricular ejection fraction

(LVEF) of 31.7%. The device demonstrated reliable performance, with an average support time of 97 minutes. Patients experienced stable hemodynamics throughout the procedure, with no major infections or MACCE events, and were successfully weaned from the device post-procedure. These early outcomes highlight NyokAssist™'s potential to offer adequate hemodynamic support during complex interventions while maintaining a favorable safety profile.

Case: High-Risk PCI with NyokAssist™ in a patient with severe LV dysfunction and Iliac artery stenosis

A 50-year-old male with heart failure (EF 31.4%), diabetes, and prior stroke presented with worsening chest symptoms. Imaging showed triple-vessel coronary disease and severe bilateral iliac artery stenosis, with the left iliac artery as narrow as ~2 mm. CABG was recommended but declined due to high surgical risk. PCI was selected. Given poor cardiac function and complex access, NyokAssist™ was used to provide circulatory support.

NyokAssist™ was safely delivered via narrow iliac arteries. It provided stable support (2.1 LPM for 1 hour and 20 minutes), with blood pressure improving from 112/79 to 137/59 mmHg, enabling the successful PCI of the LAD and LCx.

This case highlights NyokAssist™'s unique value in expanding high-risk PCI options for patients with severe PAD and limited access routes.

#### 4.Strategic Collaborations and Presence

-Clinical Partners:

Top tertiary hospitals across China (>10 centers), including those with the highest experience in ECMO, IABP, and PCI

-KOL Engagement: Close feedback loops with cardiologists, surgeons, and perfusionists in China, the U.S., and the EU

-International Trial Planning:

U.S. IDE pathway and EU MDR submission strategy under development

Ongoing dialogue with U.S. cardiac intervention networks for NyokAssist™ pilot sites

#### 5.Quality Systems & Manufacturing

-Certifications:

ISO 13485:2016

NMPA-compliant QMS (China)

-Facilities:

Fully automated in-house cleanroom for Class III MCS devices

Pilot-scale production for global trial support

**Why this drug or device is innovative, the broad implications for future research, and/or how it will improve the human condition:**

magAssist - Transforming Critical Care with the World's First Escalation-Ready

## Mechanical Circulatory Platform

magAssist is redefining cardiovascular and organ support with a first-of-its-kind mechanical circulatory platform that empowers physicians to escalate or de-escalate care using a single device. Built on a modular, interoperable architecture, the platform enables initiation of ventricular assist device (VAD), extracorporeal membrane oxygenation (ECMO), or percutaneous VAD (pVAD) support - all from the same console, with seamless bedside integration.

### One Console. Every Pathway.

Engineered for the realities of critical care, the magAssist console delivers rapid deployment, minimal disruption, and maximum flexibility. Clinicians can transition between support modes without changing hardware, reducing delays and eliminating unnecessary equipment exchanges. This unified approach streamlines training, lowers capital costs, and accelerates decision-making when every second matters.

### NyokAssist™ - A Paradigm Shift in Catheter-Based Support

NyokAssist™ combines a foldable pump, percutaneous delivery, and durable short-term performance to enable rapid use in high-risk percutaneous coronary intervention (PCI) and other acute cardiac events. In 2023, it was awarded U.S. FDA Breakthrough Device Designation for its potential to address major gaps in interventional cardiology. Its small-bore access technology responds directly to anatomical realities: more than 20% of females and 12% of males have femoral arteries under 6 mm, and 7-20% of PCI patients have peripheral arterial stenosis - groups underserved by current devices. Clinical studies in China have demonstrated procedural safety and feasibility.

### Clinician-Centered Design for Broader Access

The magAssist platform integrates intuitive interfaces, real-time monitoring, and intelligent control algorithms that reduce training time and extend advanced support capabilities beyond specialized cardiac centers. Compact, mobile consoles enable uninterrupted care as patients move between hospital units, ensuring timely intervention in fast-changing clinical situations.

### A Unified Innovation Pipeline

Beyond cardiac care, magAssist is developing an integrated ecosystem of support devices for the heart, lung, and kidney - all powered by the same modular platform. This interoperability simplifies manufacturing, accelerates scalability, and enables cross-organ data insights, laying the groundwork for the next generation of life support solutions.

### Mission in Action - Technology for Life

We believe life-saving innovation must be accessible, effective, and designed with empathy. Our mission:

- Improve patient outcomes through adaptable, innovative heart failure devices.
- Engineer the most precise, reliable organ support technologies.
- Lead the global advancement of mechanical circulatory and organ support solutions for those in critical need.

With its escalation-ready platform, proven engineering excellence, and unwavering commitment to patient-centered design, magAssist is setting a new global standard in advanced life support - offering not just more time, but a better chance for survival.

The spirit of the Prix Galien celebrates innovations that transform scientific vision into human impact. magAssist embodies that spirit - uniting breakthrough engineering with compassionate design to advance global health equity, redefine the standard of critical care, and expand what is possible for patients worldwide.

### **Please provide appropriate references (PubMed, Abstract, Website):**

1. Website: <https://en.magassist.tech/>
2. LinkedIn: [www.linkedin.com/in/magassist-china-3aa625240](https://www.linkedin.com/in/magassist-china-3aa625240)
3. Li, P., Wu, T., Hsu, P.-L., Wei, X., & Dong, N. (2022). 30-day in vivo study of a fully maglev extracorporeal ventricular assist device. *Artificial Organs*, 46(10), 2039-2047. <https://doi.org/10.1111/aor.14317>
4. Li, P., Mei, X., Ge, W., Wu, T., Zhong, M., Huan, N., Jiang, Q., Hsu, P.-L., Steinseifer, U., Dong, N., & Zhang, L. (2023). A comprehensive comparison of the in vitro hemocompatibility of extracorporeal centrifugal blood pumps. *Frontiers in Physiology*, 14, 1136545. <https://doi.org/10.3389/fphys.2023.1136545>
5. Tong, L., Wu, L., & Dong, N. (2023). Extracorporeal left ventricular assist device as a bridge to surgery for ventricular septal rupture after acute myocardial infarction. *Artificial Organs*, 47(12), 2871-2876. <https://doi.org/10.1111/aor.14561>
6. NyokAssist™ Percutaneous Ventricular Assist Device with Foldable Catheter Pump: Early Report from Clinical Trial. Shen, L. et al. *The Journal of Heart and Lung Transplantation*, Volume 44, Issue 4, S22

### **References File Document upload:**

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**2025 Prix Galien Best Startup Submission Formdraft0709.docx**

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