GB LABS

GB LABS · MEDICAL DEVICE

PainFree 8800

Business Introduction

Drug-free pain management —
six therapies in a single device

MFDS Class III combination medical device · License No. 20-20 · GMP · ISO 13485



October 2026 · Draft for review

To be finalized after verification of original licenses and certificates



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SECTION ONE

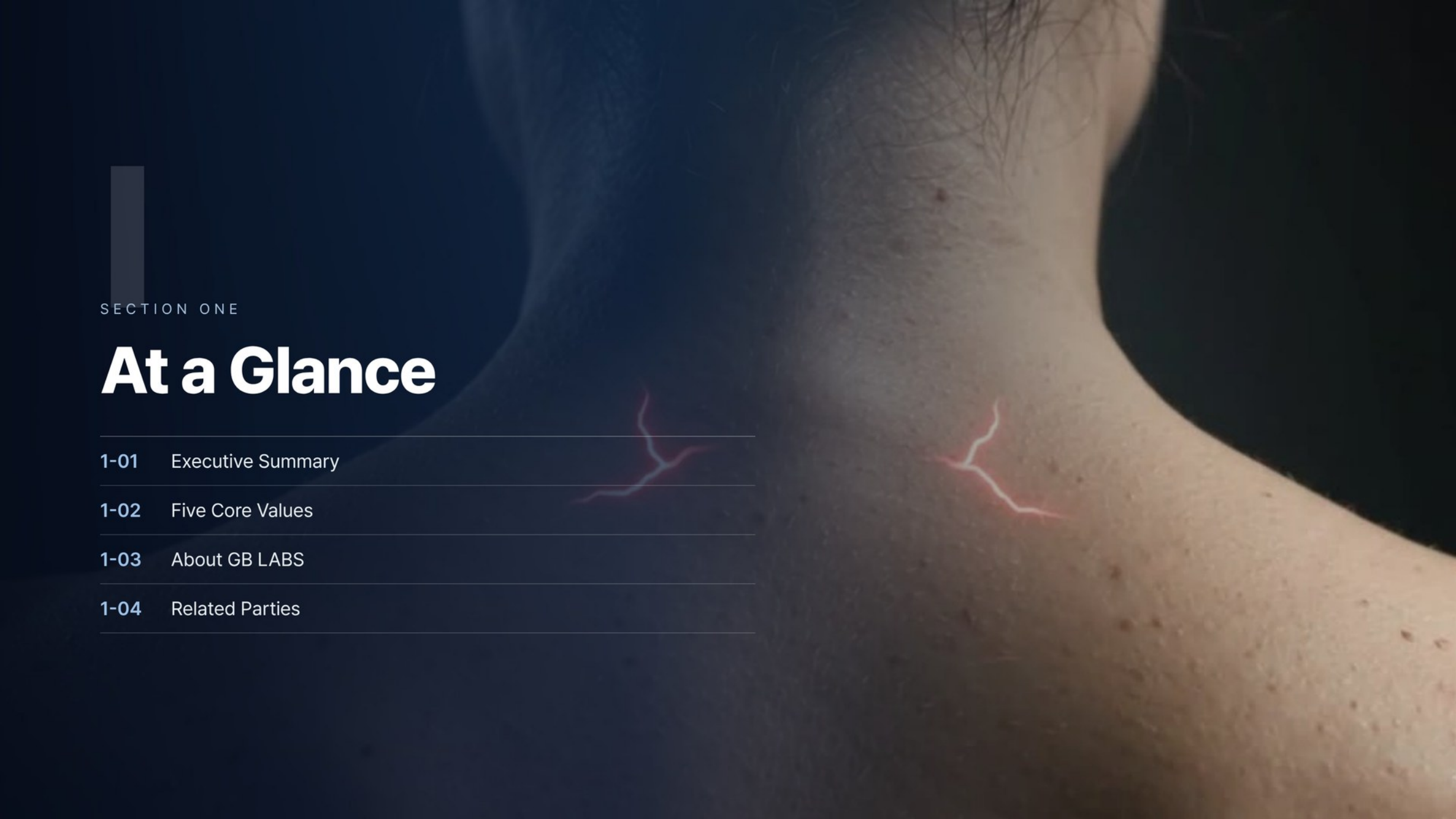
At a Glance

1-01 Executive Summary

1-02 Five Core Values

1-03 About GB LABS

1-04 Related Parties



1-01. Executive Summary

PainFree8800 at a glance

Class III

MFDS combination device · License No. 20-20

6 in 1

Electrical · Laser · Ultrasound · PEMF · Low-frequency · Thermal

GMP

KGMP conformity · ISO 13485:2016

5 IP

1 patent · 3 designs · 1 utility model



Tabletop · actual product photo



Illustrative image

Treatment at a pain clinic



Illustrative image

PainFree8800

Also held: Public Procurement Service bidder registration · KTC test 'Pass' · EMC test report · Export manufacturing license (No. 19-427)

1-02. Five Core Values

Why PainFree8800



01

Regulatory barrier

Class III domestic license, manufacturing business license and export license already in hand.



02

Six-in-one

Six licensed items in one device, led by Scrambler-type electrical stimulation.



03

Proven concept

Source technology has CE (2008), FDA (2009) and Korean New Health Technology (2013) history.



04

Ready to produce

Molds, finished units and parts on hand. (Internal estimate, before due diligence)



05

Export-ready

Export license · ISO 13485 · EMC and KTC tests · GS1 code.

Based on internal materials; figures are not stated as confirmed facts before verification. Some photos are illustrative.

1-03. About GB LABS

Company profile



CEO Lim Chun-hak
M.D., Ph.D. · Professor of Anesthesiology and Pain Medicine, Korea University

GB LABS & GBI is a digital healthcare company that develops and operates **telemedicine systems**, built on over ten years of IT experience in hospital information systems, fintech and VR/AR.

We focus on preventive, personalized health management and run medical services linking Korea and Indonesia.

A company led by a pain medicine specialist is expanding into **pain-treatment medical devices.**

HISTORY

2017.11	Began developing a digital health platform
2019.10	Founded GBI headquarters in Korea
2020.01	Established GBI Indonesia
2022.04	Opened DIGIDOC clinic and EONNI aesthetic clinic
2022.10	Launched DIGIDOC iOS app
2026.10	Launched PainFree8800 medical device business

1-04. Related Parties

Who does what

BUSINESS LEAD

GB LABS & GBI

Leads the PainFree8800 business
Holds 5 IP rights by assignment (GBI)
Marketing and sales channels

MANUFACTURING · LICENSE

GM · GM R&D

Manufacturing business license No. 6094
Holder of product license No. 20-20
Operates GMP · ISO 13485

EXPORT OEM

Solco Hitech

Listed as contract manufacturer
on export license No. 19-427

Licenses are held by sole proprietor **GM**; IP has been assigned to **GBI**. Transferring licenses to a new corporation and organizing IP is the first step to commercialization.







SECTION TWO

Product

2-01 Product Overview

2-02 Device and Components

2-03 Tabletop and Stand

2-04 Installation Checklist



2-01. PainFree8800 Overview

Specifications



Stand type · actual product photo

Model	PainFree S8800 (naming to be unified)
Item	Transcutaneous pain-relief electrical stimulator + 5 items
License	MFDS Class III · No. 20-20 · valid to 2030.08.31
Channels	6CH (3 sets × 2CH), independent
Modes	103 low-frequency modes
Display	10.1-inch touch LCD (per official site)
Connectivity	Bluetooth 5.0 (per official site)
Power	AC 100–240V, 50/60Hz (check rating plate)

One device runs **six therapies** — without drugs or procedures, through electrodes and probes on the skin.

Specifications follow the official website and will be finalized against the approved spec sheet and user manual.

2-02. Device and Components

What comes in the box



1. Main unit
2. Electrode pads, 6 channels
3. Thermal belt
4. Laser probe
5. Ultrasound probe
6. Thermal footplate

Components may vary by supply contract; standard and optional configurations are listed separately.

2-03. Tabletop and Stand

Two forms



Tabletop

A single unit that fits on any treatment-room table.



Stand

A cart with tray, thermal belt and thermal footplate.

2-04. Installation Checklist

Before adoption



PRE-ADOPTION CHECKS

- ✓ Space, power and environment
- ✓ Patient flow and treatment position
- ✓ Staff training
- ✓ Cleaning, disinfection and consumables
- ✓ Regular inspection and repair

Together with each clinic, we document responsibilities **from installation to training and after-sales service**.

SECTION THREE

Technology

3-01 Six Modalities

3-02 How Scrambler Therapy Works

3-03 Source Technology

3-04 Level of Evidence



3-01. Six Modalities in One Device

Licensed items

01 — Class II · Core
Transcutaneous electrical stimulator
Scrambler Therapy type

02 — Class III
Medical laser
Class 3B · 3 output levels

03 — Class II
Ultrasound stimulator
1.2MHz · 3 output levels

04 — Class II
Electromagnetic generator
PEMF · up to 3,000 Gauss

05 — Class II
Low-frequency stimulator
103 modes

06 — Class II
Medical heater
Footplate and belt

A combination device takes the highest class among its items (**Class III**). Music playback and magnetized-water functions are outside the license scope.



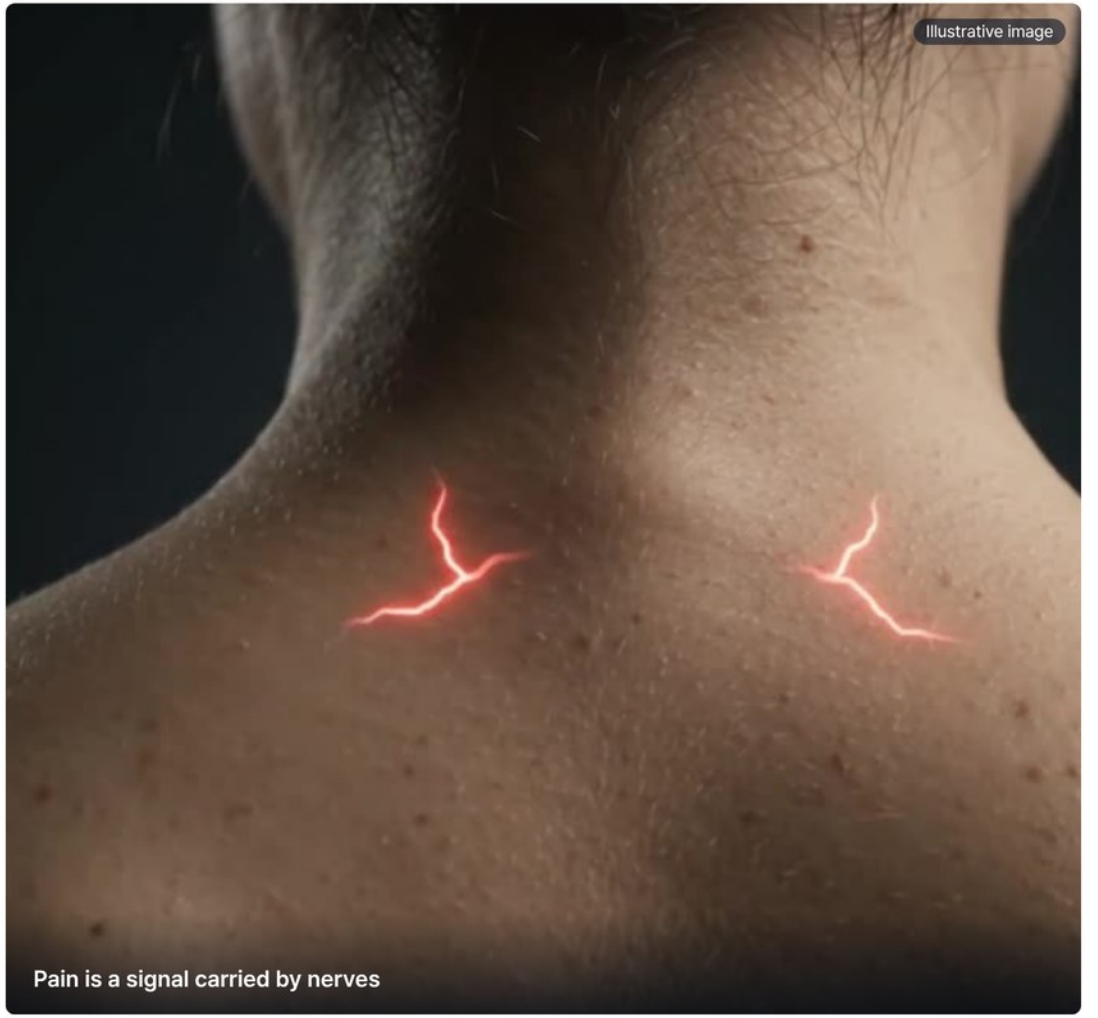
3-02. How Scrambler Therapy Works

Concept

Item	Conventional TENS	Scrambler type
Theory	Gate control	Information theory
Target fibers	A-beta	A-delta and C (pain pathways)
Mechanism	**Blocks pain signals**	**Replaces pain information with 'non-pain' signals**

Pain is a **signal** carried by nerves to the brain. The Scrambler concept sends 'non-pain' signals through skin electrodes to change the information the brain receives.

A general description of the concept, not a claim about PainFree8800's efficacy. Indications, contraindications and use follow approved documents.



3-03. Source Technology History

International and domestic

2008

CE marking

Europe (source device)

2009

US FDA

510(k) (source device)

2012

New item in Korea

Transcutaneous pain-relief stimulator

2013

New Health Technology

Ministry of Health and Welfare

2014

Fee schedule

Procedure code MZ012

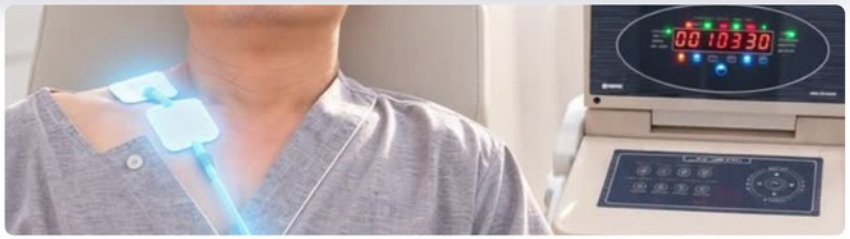
2023

NEJM review

Smith & Wang

This history refers to the source device (Calmare MC-5A). **PainFree8800's own licenses are covered in Section IV.**





3-04. Current Level of Evidence

What we know

CONFIRMED

· New Health Technology (2013)

· Fee schedule code MZ012

· CE and FDA history of source device

· Record of use at Korean institutions

LIMITATIONS

· No published clinical study of PainFree8800 itself

· Source-technology studies are small with mixed results

· No efficacy claims until evidence is confirmed

PLAN

· 1–2 investigator-initiated trials

· Usability study and publication

· Evidence grading for each claim

· Advertising claims register





IV

SECTION FOUR

Licenses · Quality · IP

4-01 Manufacturing and Export Licenses

4-02 Quality and Safety

4-03 Document Gallery

4-04 Intellectual Property



4-01. Manufacturing and Export Licenses

Licenses

MANUFACTURING BUSINESS

No. 6094

Licensed 2018.05.23

DOMESTIC PRODUCT

No. 20-20

6 items · Class III · valid to 2030.08.31 (renewable)

EXPORT

No. 19-427

2019.07.03 · PAINFREE-S8800 · 5 items



의료기기 제조 허가증



의료기기 제조 허가증

The export license lists the contract manufacturer (Solco Hitech) as manufacturer; holder details will be aligned.

4-02. Quality and Safety Certificates

Quality

Item	No. · Date	Note
KGMP	**KCL-ABBA-17521 · 2023.06**	**Renewed 2026 (evidence pending)**
ISO 13485	**23-B-1655 · 2023.08**	**Renewed 2026 (evidence pending)**
KTC test	GME2022-10030(R2)	'Pass' · class code to verify
EMC	Bureau Veritas · 2023.03	IEC 60601-1-2 edition check
Procurement	2023.12 · renewed 2024.06	Public procurement channel
GS1 code	88001644 · to 2027.06	Product identification



4-03. Document Gallery

Supporting documents (Korean originals)



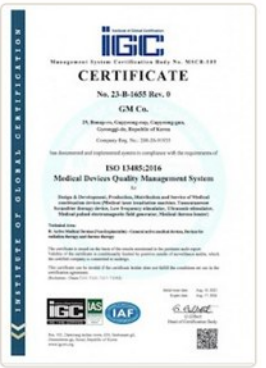
Product license



Export license



KGMP



ISO 13485



KTC test



EMC



Procurement



Patent



Design



Utility model

Reduced copies for viewing. Inventors' personal details are masked. Originals available on request.

4-04. Intellectual Property

Patents and designs

Type	No.	Title	Expiry
Patent	**10-2171563**	**Transcutaneous pain-relief electrical stimulator**	**2039.03**
Design	**30-1048945**	**Medical electrical stimulator**	**2039.05**
Utility	20-0498200	Activated magnetized drinking-water generator	2034.03
Design	30-1235906	Magnetized-water device	2043.02
Design	30-1235910	Magnetized-water device	2043.02

Rights have been **assigned from the inventor to GBI**. Change of registered owner at KIPO is being confirmed.

The three magnetized-water rights will be included only after their relevance to PainFree8800 is confirmed.



V

SECTION FIVE

Market & Business

5-01 Aging and Pain Management Demand

5-02 Positioning and Customers

5-03 Revenue Model

5-04 Roadmap

5-05 Risks and Responses

5-01. Aging Drives Pain Management Demand

Market demand

20%

Share of Koreans aged 65+ (Dec 2024, super-aged society)

~10%

Adult chronic pain prevalence (estimate, varies by survey)

$5.8B

Global pain management devices market by 2029 · 9.1% CAGR

As the population ages, demand grows for **long-term, drug-free pain management**. Long-term care and rehabilitation hospitals and pain clinics are the first markets.

Forecasts are third-party estimates (MarketsandMarkets) and do not represent PainFree8800 revenue.



5-02. Positioning and Target Customers

Positioning

VS. COMPETING DEVICES

Item	Competitors	PainFree8800
Price range	~KRW 38–80 million	By negotiation
License	Mostly single item	**Six-item combination**
Core tech	Separate device per therapy	**Includes Scrambler type**

Adoption metric: **revenue per treatment × utilization ÷ device cost**

TARGET CUSTOMERS

Clinics

Pain medicine · orthopedics · rehabilitation

Long-term care hospitals

Patients needing ongoing pain care

Cancer & palliative

Under review

Public procurement

Public and veterans' hospitals



Customer groups are sales hypotheses, not confirmed contracts. Case studies are published only with institutional approval.

5-03. Six Revenue Streams

Business model

01
Device sales
Direct sales and distributors

02
Rental · lease
Monthly plans to lower upfront cost

03
Consumables
Recurring electrode pad sales

04
Public procurement
Procurement Service channel

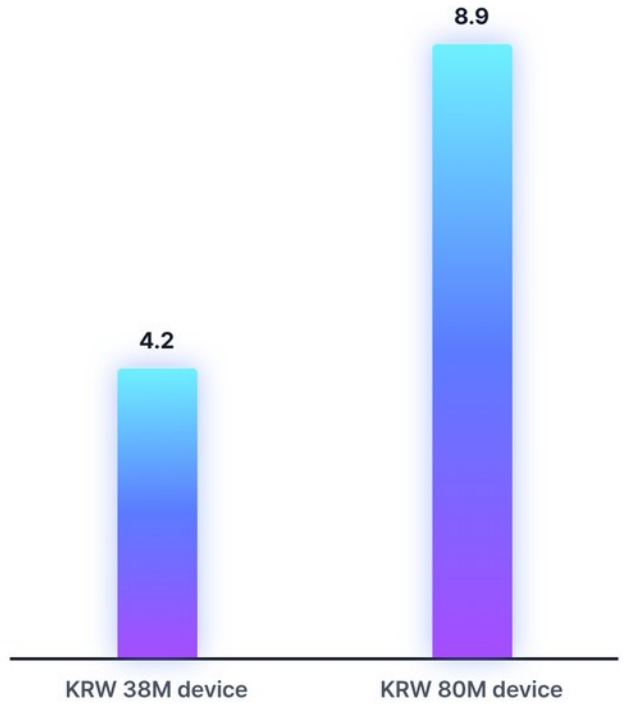
05
Export
Based on export license

06
Training · service
User training and maintenance

Clinic example (assumption): KRW 150,000 × 3 patients/day × 20 days = **KRW 9 million/month** → payback ~4.2 months on a KRW 38M device, ~8.9 months on KRW 80M

A simple example using competitor price ranges; excludes labor and consumables; not PainFree8800's price.

PAYBACK EXAMPLE (MONTHS)



5-04. 36-Month Roadmap

Roadmap

Phase 1 · 0–12 months

Foundation

License transfer and renewals, claim review, 1–2 pilot sites

Phase 2 · 13–24 months

Evidence and growth

Investigator-initiated trials, procurement, domestic sales network

Phase 3 · 25–36 months

Global

Export partners after local regulatory review

M+3
Incorporation · IP and license transfer

M+6
R&D center · IIT approval · rental launch

M+12
First procurement delivery · interim results

M+24
Revenue track record · overseas certification

M+36
First export contract · next model





Timelines are targets and may change with negotiations and regulatory progress.



5-05. Key Risks and Responses

Risks

Risk	Description	Response
Regulatory	Licenses held by a sole proprietor; manufacturer naming mismatch	Transfer to a new corporation before investment
Renewal	GMP and ISO renewal in 2026	Renewal evidence as a precondition
Claims	Efficacy claims beyond licensed scope	Wording aligned with licensed intended use · claims register
Clinical	Limited product-specific evidence	Investigator-initiated trials and publication
Market	Slow adoption, competitor pricing	Rental and pilot programs
Key person · finance	Reliance on key staff · working capital and inventory	Organization building · milestone-based funding







NEXT STEPS

Stand tall again.

01 Verify
Review original licenses and certificates

02 Organize
Holder transfer · renewals · claims

03 Pilot
Field use with partner clinics

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gblabs.co.kr



This is a draft for review, not an investment solicitation. 'Illustrative image' marks AI-generated images; only 'actual product photos' show the real device.