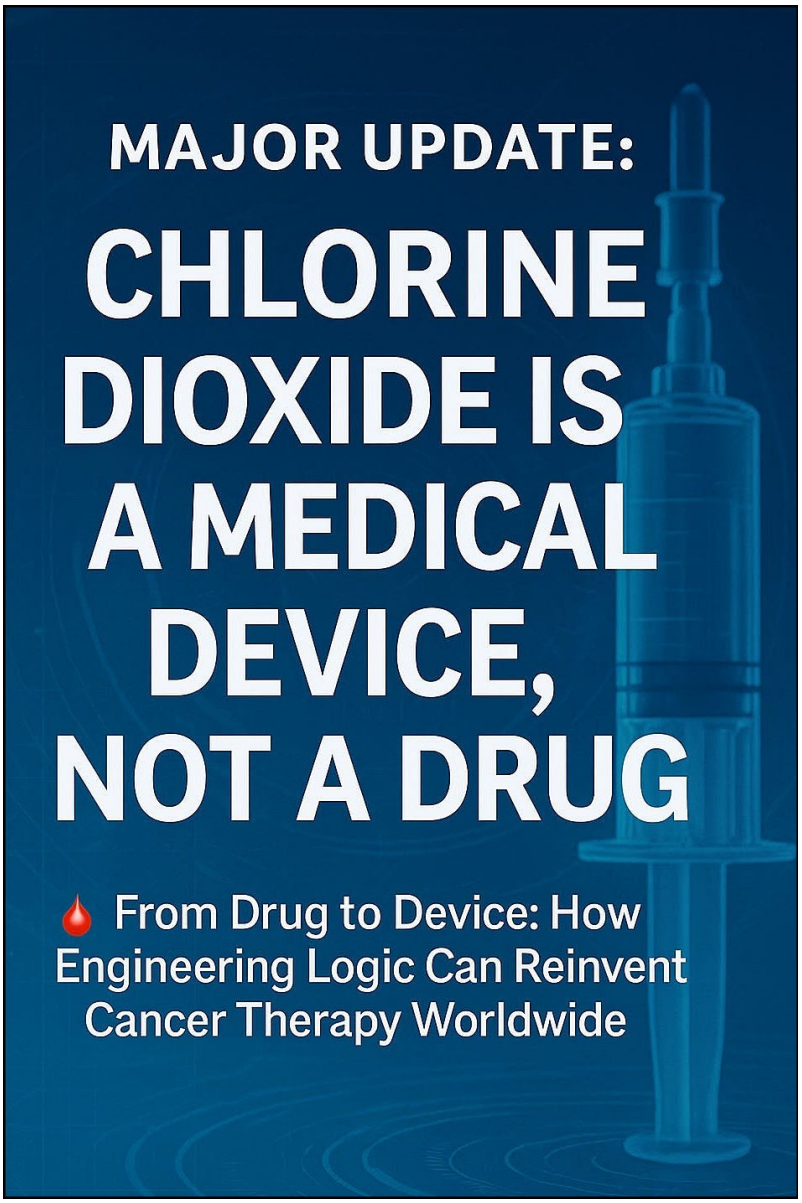
Intra-Tumoral ClO_2

Major Update: Chlorine Dioxide Is a Medical Device, Not a Drug

🩸 From Drug to Device: How Engineering Logic Can Reinvent Cancer Therapy Worldwide.

Xuewu Liu Oct 28, 2025 · Paid



For years, I believed that **Intratumoral Chlorine Dioxide Therapy (Intra-ClO_2 Therapy)** had to follow the pharmaceutical drug path — requiring extensive pharmacological studies, systemic efficacy endpoints, and multi-phase clinical trials.

After months of cross-referencing the laws and regulatory definitions in **China, the European Union, and the United States**, I realized something game-changing:

Chlorine dioxide, when used for local tumor ablation, does not act pharmacologically, immunologically, or metabolically.

It achieves its therapeutic purpose through physico-chemical oxidation, making it a Class III medical device — not a drug.

This discovery changes everything.

It means our path to clinical approval is **shorter, safer, and far more feasible worldwide**.

It also reframes this therapy as an **engineering-based cancer solution**, rather than a chemical drug.

CN China: Class III Medical Device + Order 818 Biomedical New Technology

Dual-Track Strategy for Rapid Approval

Under China's *Regulations on the Supervision and Administration of Medical Devices*, a medical device's primary intended action must *not* be achieved through pharmacological, immunological, or metabolic means.

By contrast, the *Drug Administration Law* requires that drugs *modulate physiological functions* intentionally.

Intratumoral chlorine dioxide works through **non-selective oxidation**, causing localized necrosis and collapse of the tumor's internal structure — a **physico-chemical ablation process** identical in logic to radio frequency, microwave, or cryo-ablation devices.

Therefore, it qualifies as a **Class III medical device (high-risk)**, not a pharmaceutical drug.

I am now pursuing **two synchronized application tracks**:

1. **Innovative Medical Device Registration (NMPA)** –
   > Product name: *Intratumoral Chlorine Dioxide Ablation System*

2. **Order 818 Filing (National Health Commission)** –
   > As a *new biomedical technology* for local oxidative ablation.

Together, these routes will allow lawful clinical translation inside China — faster and more transparently than any drug pathway.

EU **European Union: Substance-Based Device under MDR 2017/745**

Falling squarely within EU "non-pharmacological" classification

The EU Medical Device Regulation (MDR 2017/745) defines devices as products whose primary intended action is *not* achieved by pharmacological, immunological, or metabolic means.

Chlorine dioxide's effect — *chemical ablation of tissue through oxidation* is a **physical destruction**, not a modulation of physiology.

It thus qualifies as a **"substance-based medical device"**, a category that already includes:

- Hemostatic gels
- Tissue adhesives and sealants
- Chemical cauterization or irrigation fluids

Under MDR 2017/745, the chlorine dioxide ablation system would be registered as a **Class III device**, evaluated mainly on **local safety, controllability, and reproducibility** — typically achievable within **2–3 years**, not 8–10 years like drugs.

US **United States: Consistent with FDA's "Non-Chemical Action" Definition**

Clear alignment with FDA's 2011 Chemical Action Guidance

Section 201(h) of the *U.S. Federal Food, Drug and Cosmetic Act* states:

A product is *not* a device if it "achieves its primary intended purposes through chemical action within or on the body."

But the FDA's 2011 draft guidance clarified:

The *presence* of a chemical reaction ≠ "chemical action."

It counts only if the reaction *mediates a bodily response* or *alters an entity's properties*.

Chlorine dioxide does neither.

It does not bind receptors, alter metabolism, or modulate immunity — it **physically destroys target tissue** via oxidation, then decomposes to inert salts.

The FDA offers analogies:

- **Dental filling materials** form covalent bonds yet are devices.
- **Bone cement** causes exothermic polymerization yet is a device.

By the same logic, chlorine dioxide's tissue ablation is a **device-type physico-chemical process** — qualifying it for **PMA or De Novo device approval**.

🧭 Why the Device Pathway Is Faster and More Ethical

A shift from pharmacology to precision engineering.

Drug approvals focus on **systemic efficacy** and **mechanistic pharmacology**.

Medical devices, instead, are judged on **local safety**, **performance reproducibility**, and **engineering control**.

For intratumoral ClO_2 ablation:

- The evaluation endpoints are **ablation range**, **imaging visibility**, and **dose-range correlation**,
- Not long-term survival or biochemical modulation.

Ethically, **Declaration of Helsinki Article 37** states:

"Where proven interventions do not exist, physicians may use unproven interventions with informed consent, if they offer hope of saving life, re-establishing health, or alleviating suffering."

Device-based protocols align perfectly with this clause — lowering ethical barriers and giving physicians flexibility under compassionate-use principles.

🩺 Empowering Physicians: Personalized "Non-Standard" Care for Late-Stage Patients

Guided by Helsinki Article 37 and the Right-to-Try ethos:

When standard therapies fail, are inaccessible, or intolerable, physicians have a moral and legal basis to provide **individualized local ablation** using new or unapproved technologies — provided informed consent and documentation are thorough.

Our ethical framework:

- **Purpose:** localized debulking, symptom relief, or bridge to other therapy
- **Nature:** engineering-based ablation system — *not* systemic pharmacology
- **Indication:** advanced or refractory solid tumors
- **Core requirement:** image-guided, controlled dosage, predictable boundaries

Step	Key Points
Patient selection	Late-stage or recurrent, image-visible, safe access path
Guidance	Ultrasound / CT navigation, avoid vessels & hollow organs
Dosage control	Multi-point injection, ⩽ 30 % of tumor volume total
Risk management	Prepare hemostasis, drainage, infection prevention
Post-procedure	24 - 72 h imaging to confirm necrosis and safety margins

Implementation checklist:

Ethical & legal best practice:

- Label as *"individualized non-standard local therapy,"* not a "drug treatment."
- Record before/after imaging, injection parameters, complications.
- Include family participation in consent and shared decision-making.
- Whenever possible, obtain **IRB or hospital academic review** and classify cases as **Real-World Evidence (RWE)** for future publications.

Suggested consent language:

"Given that standard therapies are no longer effective or suitable, we may attempt a personalized local ablation technique. A small volume of chlorine dioxide working solution will be injected directly into the tumor under imaging guidance, with the goal of local necrosis and tumor shrinkage.

This is a non-standard therapy — potential risks and uncertainties are fully disclosed, and the decision to proceed is entirely voluntary."

🤝 Call for Collaboration

An open invitation to physicians and researchers

I warmly invite oncologists, interventional radiologists, and biomedical engineers across China, Europe, and the U.S. to participate in:

- **Multicenter clinical studies** and ethical trials
- **Case registries and real-world evidence (RWE)** collection
- **Algorithm optimization** for path planning and dose-response mapping
- **Imaging follow-up correlation** of necrosis and recovery

Together, we can build a rigorous evidence base and bring this therapy to patients faster — **scientifically, ethically, and globally.**

🌍 Next Steps: From China to Global Certification

1. **China** – Complete Innovative Medical Device application and Order 818 filing.
2. **European Union** – Register under MDR 2017/745 as a Substance-Based Class III Device.
3. **United States** – Submit PMA application, asserting "non-chemical action" classification.

Each region reinforces the same principle: **physico-chemical ablation is an engineering intervention, not a pharmaceutical one.**