

A medical appliance is an item that is used to directly substitute for a malfunctioning part of the human body. Bone growth stimulation devices are used for treatment purposes and do not qualify as medical appliances eligible for the 1% rate. See 86 Ill. Adm. Code 130.311(e). (This is a PLR).

September 5, 2025

NAME
COMPANY
ADDRESS
EMAIL

Dear NAME:

This letter is in response to your letter dated May 6, 2025, in which you requested information. The Department issues two types of letter rulings. Private Letter Rulings ("PLRs") are issued by the Department in response to specific taxpayer inquiries concerning the application of a tax statute or rule to a particular fact situation. A PLR is binding on the Department, but only as to the taxpayer who is the subject of the request for ruling and only to the extent the facts recited in the PLR are correct and complete. Persons seeking PLRs must comply with the procedures for PLRs found in the Department's regulations at 2 Ill. Adm. Code 1200.110. The purpose of a General Information Letter ("GIL") is to direct taxpayers to Department regulations or other sources of information regarding the topic about which they have inquired. A GIL is not a statement of Department policy and is not binding on the Department. See 2 Ill. Adm. Code 1200.120. You may access our website at <https://tax.illinois.gov/> to review regulations, letter rulings and other types of information relevant to your inquiry.

Review of your request disclosed that all the information described in paragraphs 1 through 8 of Section 1200.110 appears to be contained in your request. This Private Letter Ruling will bind the Department only with respect to COMPANY, for the issue or issues presented in this ruling, and is subject to the provisions of subsection (e) of Section 1200.110 governing expiration of Private Letter Rulings. Issuance of this ruling is conditioned upon the understanding that neither COMPANY, nor a related taxpayer is currently under audit or involved in litigation concerning the issues that are the subject of this ruling request. In your letter you have stated and made inquiry as follows:

Pursuant to 2 Ill. Admin. Code § 1200.110, COMPANY respectfully requests a Private Letter Ruling on whether its bone growth stimulation devices, including the DEVICE, DEVICE1, and DEVICE2, qualify as non-taxable "medical appliances" under Illinois law.

Issue

1. Does COMPANY's sales of bone growth stimulation devices qualify for the state's medical appliance reduced tax rate?
2. Do bone growth stimulation devices meet the definition of Illinois's medical appliance definition?
3. Currently COMPANY is billing the medical device at the full Illinois Retailer's Occupational tax.

We affirm that this matter is not currently being audited, litigated, or otherwise addressed by the Department of Revenue and that the request pertains to a specific, actual situation of the requesting taxpayer.

Statement of Facts

COMPANY, is a global provider of orthopedic medical technologies. The company's DIVISION division specializes in the treatment of non-healing bone fractures and fusions, including those of the spine. These conditions reflect a physiological malfunction in the body's bone repair systems, both at the cellular and bioelectrical level. When a bone fails to heal and a nonunion forms, this reflects not merely a delay in healing but a fundamental malfunction of the body's repair system at the cellular and biophysical levels.^{1,2,3,4}

I. The Normal Bone Healing Process^{1,5,6,7}

Bone healing is a complex, tightly regulated biological process that under normal conditions progresses through three overlapping phases. Each of these phases relies on precise cellular communication, molecular signaling, and biophysical mechanisms, particularly the body's innate piezoelectric properties.

A. Bone Healing Phases

Each of the three phases of bone healing requires precise cell signaling, vascular support, and mechanosensory feedback to proceed. Each phase relies on mesenchymal stem cell recruitment, angiogenesis, osteoblast/chondrocyte function, and piezoelectric signaling from mechanical loading. Phases and the associated timeline post-injury are shown herein:

- Inflammation Phase (Initial days post-injury)
- Repair Phase (Days to Weeks)
- Remodeling Phase (Months to Years)

B. Piezoelectric Currents

Bone is piezoelectric, meaning it generates electric potentials in response to mechanical stress due to the crystalline structure of its collagen fibers. These bioelectric signals serve critical functions in bone healing. Under normal conditions, mechanical loading (e.g., walking, movement) generates piezoelectric currents that activate and direct repair processes. These currents are integral, not supplemental, to bone healing and the phases outlined above:

- Stimulate osteoblastic activity
- Promote cellular migration and differentiation
- Guide bone remodeling and callus formation

II. Malfunction at the Cellular & Bioelectrical Levels Leads to Nonunion^{6,8,9,10}

A nonunion, typically defined as a fracture that fails to heal within 6–9 months, reflects a systematic failure in cellular coordination and bioelectrical signaling. Specific details are shown in the table below, illustrating the biologic malfunction behind nonunion:

FAILED PROCESS	UNDERLYING CAUSE	CELLULAR CONSEQUENCE
MSC Recruitment	Poor blood flow or inflammation	Insufficient chondrocyte/osteoblast formation
Angiogenesis	Disrupted VEGF signaling (e.g, ischemia, diabetes)	Poor vascular support
Chondrocyte Function	Impaired chondrogenesis	Weak Callus formation
Osteoblast Activity	Toxic inflammation, smoking, NSAIDS	Poor bone matrix deposition
Osteoclast Overactivity	Chronic inflammation	Premature resorption

Chronic Inflammation	M1 macrophage dominance	Persistent catabolic state
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In nonunion, there is a complete absence of piezoelectric signaling, often due to immobility or lack of mechanical loading, chronic inflammation or ischemia disrupting collagen structure, and systemic factors like diabetes or infection impairing signal transduction.

The consequences of disrupted piezoelectric currents include:

- Reduced recruitment and activation of osteoblasts
- Impaired mineralization and tissue remodeling
- Replacement of bone with fibrous, non-functional tissue

III. Clinical Recognition^{11,12,13,14}

The medical community recognizes this malfunction through the use of electrical stimulation therapies which **mimic and thus, “replace” the malfunctioning piezoelectric currents**. These technologies serve as an **external replacement** for what the body is unable to do based on the malfunctions identified above. These interventions are not experimental, they are supported by published pre-clinical and clinical evidence, deemed medically necessary and are covered by major health insurance plans, such as Medicare. These technologies are standard of care in cases of impaired healing, precisely because the body’s natural signaling system has failed. Without such intervention, nonunion may be considered chronic, may result in amputation, or need significant surgical intervention.

Nonunion is not a passive delay in healing, it is a pathological state arising from multi-systemic failure, including breakdowns in cellular behavior, inflammatory regulation, vascularization, and bioelectrical signaling. The absence or dysfunction of piezoelectric currents further reinforces the conclusion that a nonunion is a clear instance of the body malfunctioning at both biological and electrical levels. A nonunion is a failure of the body’s natural repair mechanisms, justifying medical, rehabilitative, and possibly legal intervention.

IV. Bone Growth Stimulation as a Means of Replacing Malfunctioning Systems in the Body^{15,17,18,19,20}

By mimicking endogenous piezoelectric currents and/or generating mechanical stresses and triggering the same biochemical cascade, bone growth stimulation therapy, inclusive of all FDA approved electromagnetic

and electric technologies, **corrects a physiological deficit**, addressing not just symptoms but the **root cause of nonunion**. It is therefore medically and legally justifiable to characterize such stimulation therapy (and the devices that deliver the therapy) as a **biophysical substitute for failed cellular and electrical mechanisms** in bone healing.

A. Combined Magnetic Field (CMF™) Inductive Coupling Electromagnetic Stimulation

COMPANY offers two products that deliver CMF™ technology, the DEVICE and DEVICE1. Extensive pre-clinical and cellular data has been published detailing how this technology replaces malfunctioning cellular pathways required for successful bone healing.

In the landmark 2001 study by Brighton et al., researchers showed that CMF therapy significantly increased osteoblast proliferation via intracellular signal transduction. CMFs stimulate the release of calcium (Ca^{2+}) from intracellular stores, raising cytosolic Ca^{2+} concentrations. This activates calmodulin, a key regulator of nucleotide synthesis and cell proliferation. CMFs bypass dysfunctional mechanotransduction by emulating piezoelectric currents, thereby reinitiating halted bone formation processes. Taken directly from the publication: "Combined electromagnetic fields... led to an increase in cytosolic Ca^{2+} and activated cytoskeletal calmodulin," directly correlating with enhanced DNA synthesis and bone cell proliferation. CMFs result in a 21–30% increase in DNA synthesis in bone cells over control, even without mechanical loading. The proliferative effect is mediated through the same final signaling pathway used by physiological strain: cytosolic $\text{Ca}^{2+} \rightarrow$ calmodulin activation $\rightarrow$ bone formation.¹⁵

Additional pre-clinical and cellular data has been provided to further support how this technology replaces malfunctioning cellular pathways required for successful bone healing.

Author	Citation & Web Link	Summary
Brighton , Carl T., et al.	"Signal Transduction in Electrically Stimulated Bone Cells." <i>The Journal of Bone and Joint Surgery. American Volume</i> , vol. 83, no. 10, 2001, pp. 1514–1523. Link to Publication	Demonstrates that combined electromagnetic fields increase cytosolic calcium and calmodulin activity in

		osteoblasts, directly enhancing DNA synthesis and cell proliferation.
Aaron, Roy K., et al.	Kaadan, A.; Salati, S.; Setti, S.; Aaron, R. Augmentation of Deficient Bone Healing by Pulsed Electromagnetic Fields From Mechanisms to Clinical Outcomes. Bioengineering 2024, 11, 1223. Link to Publication	A pre-clinical animal study showing that CMF increases bone formation in areas of stress shielding, suggesting stimulation of osteogenic pathways.
Yang, Xu, et al.	Yang, Xu et al. "Callus mineralization and maturation are delayed during fracture healing in interleukin-6 knockout mice." Bone vol. 41,6 (2007): 928-36. doi:10.1016/j.bone.2007.07.022 Link to Publication	An in vivo study in rats revealing that CMF exposure accelerates callus maturation, increases mineral apposition, and modulates gene expression related to osteogenesis.
Ryaby, James T.	"Clinical Effects of Electromagnetic and Electric Fields on Fracture Healing." <i>The Journal of Bone and Joint Surgery. American Volume</i> , vol. 83, no. 10, suppl. 2, 2001, pp. 143–151. Link to Publication	Although largely clinical, this review incorporates data from several animal and in vitro studies showing CMF

		increases in osteoblast proliferation, matrix synthesis, and bone healing rate.
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Clinical data further supports the effectiveness of CMF™ technology in replacing malfunctioning cellular pathways. In a study reviewed by FDA to approve CMF™ technology as safe and effective for the first time, patients with chronic nonunion were evaluated. The data was later published (Baumhauer). Patients had underwent, on average, 2.5 prior surgical interventions with a mean time since injury of 29.3 months. Patients had received no intervention for at least three months prior to the start of stimulation. A clinically significant outcome of 60.7% overall was achieved with 73.6% of all fractures less than two years old healing successfully and 75.6% of tibia fractures healing successfully. Additionally, 100% of the fractures were still healed 3 months post-treatment. This is clinically significant because many of the nonunions in this study were destined to undergo one or more additional surgical interventions, possible amputations, along with continuing disability and pain.²²

B. Low Intensity Pulsed Ultrasound Stimulation (LIPUS)

COMPANY offers it's newly FDA approved DEVICE2™ device designed to deliver LIPUS technology for the treatment of nonunion fracture. LIPUS emits pulsed ultrasound waves that generate nano-scale mechanical stresses at the fracture site. These stresses are detected by integrin receptors on bone cells, initiating intracellular signaling cascades that promote osteogenesis. Additionally, LIPUS induces acoustic streaming, enhancing fluid movement around cells, which increases nutrient and signaling molecule exchange, further supporting bone regeneration.²³

Upon mechanical stimulation by LIPUS, integrins activate focal adhesion kinase (FAK), leading to the upregulation of cyclooxygenase-2 (COX-2) and subsequent production of prostaglandin E2 (PGE2). PGE2 plays a crucial role in bone healing by promoting osteoblast differentiation and mineralization. This pathway mirrors the body's natural response to mechanical loading, effectively compensating for its absence in cases like immobilization or nonunion fractures.²⁴

LIPUS stimulates the expression of vascular endothelial growth factor (VEGF), promoting angiogenesis at the fracture site. This increased blood vessel formation improves oxygen and nutrient delivery, essential for tissue regeneration. Moreover, LIPUS encourages mesenchymal stem cells to differentiate into osteoblasts and chondrocytes, facilitating the formation of new bone and cartilage.²⁴

By emulating the mechanical and biochemical cues of natural bone healing, LIPUS serves as a non-invasive therapeutic option to stimulate bone repair, especially in scenarios where the body's healing processes are compromised. Its ability to activate key signaling pathways and promote cellular activities underscores its role as a functional replacement for impaired biological mechanisms in bone regeneration.

Clinical data further supports the information provided. In a study published in 2015, heal rate for chronic (>1 year) nonunion patients (N=767) treated with LIPUS was 86.2%. Heal rate was 82.7% among 98 patients with chronic nonunion ≥5 years duration, and 12 patients healed after chronic nonunion >10 years (HR=63.2%).²⁵

V. Regulatory Classification and Prescribing Requirements^{26,27,28,29}

Bone growth stimulation devices, commonly referred to as an osteogenesis stimulator, DEVICE1, DEVICE, and DEVICE2™ are provided by prescription only, on a single-patient-use basis, by COMPANY, to patients whose fractures or spinal fusions are not healing properly after documented injury or surgery. These devices emit low-level electrical pulses that stimulate bone healing, triggering cellular processes that are necessary for bone regeneration. This mechanism mimics the natural electrical signals produced by the body during normal bone healing, which in these patient populations, is insufficient to heal the bone effectively on its own.

Bone growth stimulators are classified as Class III FDA medical devices, the same classification as heart pacemakers. Class III devices are those that pose the highest risk to patient safety and are subject to the most rigorous regulatory oversight, including pre-market approval (PMA) processes. **This classification is reserved for devices that play critical roles in restoring or maintaining bodily function and, as such, must meet strict safety and efficacy standards before they can be marketed to the public.**

Patients that undergo treatment with a bone growth stimulator are required to adhere to a strict daily use schedule. The DEVICE and DEVICE1 are worn by

patients for 30 minutes per day. The DEVICE2™ is worn by patients for 20 minutes per day. Each device is equipped with a monitoring program that displays patient use information that may be accessed by the physician. Patients are trained by the physician or company representative to ensure proper placement of the device directly over the site of the injury. Patients may utilize a single device for up to nine (9) months or until the prescribing physician deems them successfully healed.

Links to the product Information for Use (IFU) as per the FDA have been included:

- DEVICE: LINK
- DEVICE1:LINK1
- DEVICE2: LINK2

The alternative to using such devices, in many instances, is surgical intervention. Many patients with conditions such as those noted by the AAOS are poor candidates for surgical intervention making treatment with bone growth stimulation their only viable option for healing. In some instances, injuries are deemed traumatic enough for physicians to utilize bone growth stimulation in addition to surgical intervention.

Similar to pacemakers, which regulate heart rhythm, **bone growth stimulators are critical in addressing a malfunctioning body part, specifically, bones that cannot heal on their own.** These devices are reimbursable by the Centers for Medicare and Medicaid Services (CMS) for the treatment of nonunion fractures, failed fusions, or high-risk spinal fusions.⁴ Other examples of Class III medical devices that qualify as medical appliances include:

- Artificial Limbs: Substitutes for lost limbs due to trauma or congenital defects
- Dental Prosthetics: Replace missing or damaged teeth
- Breast Implants: Restore breast tissue after mastectomy
- Dialysis Machines: Replace kidney function in patients with renal failure
- Orthopedic Braces and Crutches: Support and stabilize bones and joints during recovery

VI. Conclusion of Taxpayer's View

After reviewing the definition of medical appliance under Illinois tax law section 130.311, COMPANY opinion is that bone growth stimulators directly substitute for or support a malfunctioning part of the body, fulfilling the

requirements of a medical appliance under both FDA regulation and Illinois tax law Section 130.311.

VII. Supporting Information

Supporting Documents

Attached herein are copies of all relevant contracts, licenses, agreements, instruments, or other documents related to the request. These documents provide a full and accurate representation of the transaction.

VIII. References

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3. J. Sun, W. Xie, Y. Wu, Z. Li, Y. Li, Accelerated Bone Healing via Electrical Stimulation. *Adv. Sci.* 2024, 2404190. [Link to Publication](#)
4. Ding, Zi-Chuan et al. "Molecular pathogenesis of fracture nonunion." *Journal of orthopaedic translation* vol. 14 45-56. 31 May. 2018, doi:10.1016/j.jot.2018.05.002 [Link to Publication](#)
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7. Marsell, Richard, and Thomas A Einhorn. "The biology of fracture healing." *Injury* vol. 42,6 (2011): 551-5. doi:10.1016/j.injury.2011.03.031 [Link to Publication](#)
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9. Raggatt, L. J., and N. C. Partridge. "Cellular and Molecular Mechanisms of Bone Remodeling." *Journal of Biological Chemistry*, vol. 285, no. 33, 2010, pp. 25103–25108. [Link to Publication](#).
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12. Bassett, Colin A. L., et al. "Use of Pulsing Electromagnetic Fields in the Treatment of Ununited Fractures and Failed Arthrodeses." *The Journal of the American Medical Association (JAMA)*, vol. 243, no. 10, 1980, pp. 1045–1049. [Link to Publication](#)
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14. Griffin, Xavier L., et al. "Electromagnetic Field Stimulation for Treating Delayed Union or Non-union of Long Bone Fractures in Adults." *Cochrane Database of Systematic Reviews*, no. 4, 2011, Art. No.: CD008471. [Link to Publication](#).
15. Brighton, Carl T., et al. "Signal Transduction in Electrically Stimulated Bone Cells." *The Journal of Bone and Joint Surgery. American Volume*, vol. 83, no. 10, 2001, pp. 1514–1523. [Link to Article](#)
16. Claes, Lutz, and Christiane W. Wilke. "Effects of Mechanical and Biophysical Stimuli on the Fracture Healing Process." *Clinical Orthopaedics and Related Research*, vol. 355, 1998, pp. S132–S147. [Link to Publication](#)
17. Pilla, A A et al. "Non-invasive low-intensity pulsed ultrasound accelerates bone healing in the rabbit." *Journal of orthopaedic trauma* vol. 4,3 (1990): 246-53. doi:10.1097/00005131-199004030-00002 [Link to Publication](#)
18. Duarte, Luis R. "The Stimulation of Bone Growth by Ultrasound." *Archives of Orthopaedic and Traumatic Surgery*, vol. 101, no. 3, 1983, pp. 153–159. [Link to Publication](#)
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23. Palanisamy P, Alam M, Li S, Chow SKH, Zheng YP. Low-Intensity Pulsed Ultrasound Stimulation for Bone Fractures Healing: A Review. J Ultrasound Med. 2022 Mar;41(3):547-563. doi: 10.1002/jum.15738. Epub 2021 May 5. PMID: 33949710; PMCID: PMC9290611. [Link to Publication](#)
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25. DEVICE Information for Use Document – LINK3
https://enovis.com/sites/default/files/13-2109-OL1000_family_RevA.pdf
26. DEVICE1 Information for Use Document - LINK4
27. DEVICE2 Information for Use Document - ATTACHED
28. FDA Classification of Osteogenesis Stimulator devices:
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?id=5091>

Tax Period at Issue

The tax period at issue is 04/21/2022 – 04/21/2025. Furthermore, there is no litigation or audit pending.

Prior Rulings

To the best of the knowledge of both the taxpayer and the taxpayer's representative, the Department has not previously issued a ruling on the same or a similar issue for the taxpayer or a predecessor.

Authorities Contrary to the Taxpayer's Views

To the best of our knowledge, there are no authorities contrary to our views. If the Department determines there are contrary authorities, we request the opportunity to address them.

Request for Deletion of Trade Secret Information

We request that the following specific trade secret information be excluded from the publicly disseminated version of the ruling: Company names: COMPANY1 & COMPANY; Product names: DEVICE1, DEVICE, DEVICE2™.

Signature of Taxpayer or Representative

This request is made on behalf of COMPANY, and is signed by the undersigned employee, who is duly authorized to submit this request.

We understand that private letter rulings are binding only under the current law and facts and that they may be revoked or cease to bind the Department in the future under certain circumstances. We also understand the Department's policy on the expiration and revocation of private letter rulings as outlined in Section 4 of the Taxpayer's Bill of Rights Act (20 ILCS 2520/4) and related provisions.

Thank you for your consideration of this request. Should you require any further information or documentation, please do not hesitate to contact me, NAME, EMAIL.

DEPARTMENT'S RESPONSE:

The Illinois Retailers' Occupation Tax Act imposes a tax upon persons engaged in this State in the business of selling tangible personal property to purchasers for use or consumption. 35 ILCS 120/2; 86 Ill. Adm. Code 130.101. In Illinois, Use Tax is imposed on the privilege of using, in this State, any kind of tangible personal property that is purchased anywhere at retail from a retailer. 35 ILCS 105/3; 86 Ill. Adm. Code 150.101.

The Department's administrative rules found at 86 Ill. Adm. Code Section 130.311 govern the taxation of Drugs, Medicines, Medical Appliances, and Grooming and Hygiene Products. Products that qualify as drugs, medicines, or medical appliances are taxed at a lower State rate of 1% plus any applicable local taxes. Items that do not qualify for the low rate of tax are taxed at the general merchandise State rate of 6.25% plus any applicable local taxes.

A medical appliance is an item that is used to directly substitute for a malfunctioning part of the human body. 86 Ill. Adm. Code 130.311(e). Medical appliances include such items as heart pacemakers, artificial limbs, dental prosthetics and orthodontic braces, crutches, dialysis machines (including the dialyzer), and wheelchairs. 86 Ill. Adm. Code 130.311(e)(1). Corrective medical appliances such as hearing aids, eyeglasses, contact

September 5, 2025

lenses, and orthopedic braces also qualify as medical appliances. 86 Ill. Adm. Code 130.311(e)(2). Other medical tools, devices, and equipment such as x-ray machines, laboratory equipment, and surgical instruments that may be used in the treatment of patients but that do not directly substitute for a malfunctioning part of the human body do not qualify as medical appliances. 86 Ill. Adm. Code 130.311(e)(5).

As a general proposition, diagnostic, treatment, and rehabilitative equipment items do not qualify for the reduced rate of tax as medical appliances because such items are not “for use in directly substituting for a malfunctioning part of the body,” 86 Ill. Adm. Code 130.310(c)(2). Nor are such items corrective medical appliances such as hearing aids or glasses. The Department has previously stated that items that do not qualify for the lower rate are diagnostic items such as x-ray machines and laboratory equipment; and treatment or rehabilitation devices such as TENS (Transcutaneous Electrical Nerve Stimulation), NMES (Neuromuscular Electrical Stimulation), and sEMG (Surface Electromyography Systems) devices. See ST 98-00157-GIL.

Based on the information provided, it is the Department’s opinion that COMPANY’s products: DEVICE1, DEVICE, and DEVICE2 are used for treatment purposes and do not qualify as medical appliances eligible for the 1% rate.

If you have further questions concerning this Private Letter Ruling, you may contact me at (217) 782-7055. If you have further questions related to the Illinois sales tax laws, please visit our website at <https://tax.illinois.gov/> or contact the Department’s Taxpayer Information Division at (800) 732-8866.

Very truly yours,

Samuel J. Moore
Chairman, Private Letter Ruling Committee

SJM:slc