LCD RECONSIDERATION REQUEST PACKAGE

Request to Revise Medicare LCD L33317 – External Breast Prostheses
Coverage of HCPCS L8031 – External Breast Prosthesis, Silicone with Integral Adhesive
Submitted to: Medicare DME MACs CGS & Noridian
Submitted by: Aspen Consulting Service on behalf of Amoena USA Corporation

POLICY SUBMISSION

Date: 11/02/2025
To: CGS Administrators, LLC (DME MAC JB & JC) • Noridian Healthcare Solutions, LLC (DME MAC JA & JD)

From:
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(on behalf of Amoena USA Corporation)
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Subject: Formal LCD Reconsideration Request – Remove Noncoverage for HCPCS L8031 and Establish Full Coverage under SSA §1861(s)(8)

Dear CGS and Noridian DME MAC Medical Directors:

Aspen Consulting Service, on behalf of **Amoena USA Corporation**, respectfully submits this **formal request for reconsideration** of **Local Coverage Determination (LCD) L33317 – External Breast Prostheses** pursuant to **Section 1869(f)(5) of the Social Security Act** and the **CMS Program Integrity Manual (Pub. 100-08, Chapter 13)**.

Amoena USA Corporation is a manufacturer of Breast Prosetic devices and does business in all 50 States, territories as well as Worldwide.

This request seeks three actions: (1) **immediate removal** of **HCPCS L8031** from LCD L33317's **noncoverage** section; (2) recognition of **full Medicare coverage** for **HCPCS L8031** under the **Medicare Part B Prosthetic Device benefit(SSA §1861(s)(8))**, consistent with L8030; and (3) correction of policy language that currently asserts **no clinical advantage** for L8031 **without citing evidence**, which is **noncompliant** with the **21st Century Cures Act §4009**(transparency and evidence basis) and **42 U.S.C. §1395y(a)(1)(A)** ("reasonable and necessary" standard).

Executive Summary. HCPCS **L8031** replaces the surgically absent breast and differs from L8030 only in **method of suspension** (integral adhesive vs pocketed). Peer-reviewed studies demonstrate **functional advantages** (better weight distribution, reduced neck/shoulder strain, improved stability) and **psychosocial benefits** (body image, daily confidence). The LCD's current noncoverage statement cites **no medical evidence**—a deficiency at odds with federal requirements. We therefore request **immediate administrative correction** to remove L8031 from noncoverage during reconsideration, and adoption of the **proposed coverage language** (included in the package) that aligns with **SSA §1861(s)(8)**, **CMS equity goals**, and **NCCN/ASCO survivorship guidance**.

Respectfully,
Shane R. Mull, MD
Chief Medical Officer, Aspen Consulting Service
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Medical Necessity Argument

The medical necessity of **HCPCS L8031** is clear and well supported by both **clinical function** and **rehabilitative purpose** after mastectomy. Medicare coverage criteria require that an item be **reasonable and necessary** to diagnose or treat a medical condition (42 U.S.C. §1395y(a)(1)(A)), and **L8031 meets this requirement** for a defined clinical population.

Medical Purpose

L8031 is prescribed for **post-mastectomy patients to restore chest wall symmetry, improve functional posture, and enable normal daily activity following the surgical removal of one or both breasts.** The loss of breast tissue shifts body weight laterally, resulting in **torque across the cervical spine, compensatory posture imbalance, and musculoskeletal strain**. Prosthetic breast restoration is therefore **not cosmetic**, but rather **restorative and rehabilitative**—which places L8031 firmly within the **Medicare prosthetic device benefit** as defined by **SSA §1861(s)(8)**.

Clinical Indications

Evidence and clinical practice guidelines demonstrate that **adhesive breast prostheses** (L8031) are medically appropriate in cases where traditional bra-suspended prostheses (L8030) are **contraindicated or poorly tolerated** due to:

- Shoulder or neck pain from strap loading
- Post-mastectomy pain syndrome or chest wall nerve sensitivity
- Axillary scarring or fibrosis limiting shoulder motion
- Prosthesis displacement during normal activity
- Skin irritation from breast form movement
- Lymphedema aggravated by bra pressure
- Posture imbalance and spinal compensation

These are **clinical, not cosmetic**, indications. Denying access to L8031 **ignores medical need** and **imposes unnecessary physical harm** on Medicare beneficiaries recovering from breast cancer.

Section 2: Functional & Biomechanical Justification

A primary clinical advantage of **HCPCS L8031** is its ability to **stabilize prosthetic weight distribution** and improve **postural alignment**, reducing **musculoskeletal strain** after

mastectomy. Unlike gravity-dependent prostheses (**L8030**), which rely entirely on bra suspension and place weight on the shoulders, **L8031 adheres directly to the chest wall**, allowing weight to be **evenly distributed with biomechanical accuracy**.

How L8031 Improves Physical Function

Functional Issue (Without Prosthesis or L8030)	Effect of L8031
Shoulder and neck overloading from bra straps	Transfers weight to the thoracic wall, **reducing trapezius strain**
Lateral shift in trunk center of gravity	Restores balance and **reduces compensatory spinal curvature**
Prosthesis movement during walking/bending	**Fixed adhesion** prevents lateral shifting and displacement
Discomfort with arm motion due to dragging breast form	**Adhesion prevents prosthesis drag**, restoring range of motion
Balance problems causing fatigue and postural pain	Promotes **upright posture** and decreased fatigue

Peer-Reviewed Biomechanical Evidence

- **Hackethal et al. (2004)** documented that **adhesive suspension reduces shoulder strain and spinal loading**, decreasing overcompensation of cervical stabilizer muscles.
- **Münstedt et al. (1998)** found improved weight distribution and prosthesis stabilization with adhesive forms compared to pocketed bras.
- **Qiu et al. (2020)** demonstrated that women using adhesive prostheses **performed daily movements more confidently** and reported **less prosthesis displacement**.

CMS Relevance

Medicare covers prosthetic devices when they **restore functional performance** (Medicare NCD Manual §280.1). Adhesive prostheses **restore biomechanics more effectively** than standard silicone forms, making L8031 **clinically superior for certain patients** and **reasonable and necessary** under the statute.

Section 3: Psychosocial and Survivorship Justification

Following mastectomy, restoration of body form is a **core element of oncologic rehabilitation**, not a cosmetic preference. Adhesive external breast prostheses (**HCPCS L8031**) deliver **measurable psychosocial benefits** that translate into **health outcomes Medicare recognizes**—including improved adherence to care, decreased anxiety, and better social and physical participation.

A. Domains of Psychosocial Benefit

- **Body image restoration:** Patients report the adhesive form "feels part of the body," reducing constant awareness and stigma in daily life.
- **Fear-of-displacement relief:** Secure adhesion mitigates worry about shifting or visible asymmetry during activity, improving confidence in social and work settings.
- **Sexual and intimate well-being:** Natural feel and stability support partner intimacy and self-esteem.
- **Return to community participation:** Less prosthesis management burden enables resumption of exercise, volunteer work, and caregiving roles.

B. Evidence Base Supporting Psychosocial Outcomes

- **Thijs-Boer et al. (2001):** Majority preference for adhesive prostheses driven by *natural integration* and comfort, which are primary drivers of body-image recovery.
- **Münstedt et al. (1998/1996):** High recommendation rates and reports of "natural movement," enabling normal clothing choices and social re-engagement.
- **Fitch et al. (2012); Jetha et al. (2017):** Qualitative data show improved confidence, decreased distress, and enhanced day-to-day functioning with modern (including adhesive) external prostheses.

C. Alignment with Survivorship Standards

- **NCCN Survivorship** and **ASCO Survivorship** guidance endorse addressing body-image distress and offering prosthetic restoration when reconstruction is not chosen or feasible. L8031 directly advances these goals for patients who cannot tolerate pocketed forms (L8030) due to pain, lymphedema, or instability.

D. Medicare Relevance

- Under **42 U.S.C. §1395y(a)(1)(A)**, outcomes that restore function and reduce morbidity—including **mental health and quality-of-life domains**—are part of "reasonable and necessary."
- The **CMS Health Equity Framework (2022–2032)** commits Medicare to remove barriers that **disproportionately burden women**. Denial of L8031 uniquely harms female beneficiaries recovering from cancer, particularly those with bra intolerance, chest-wall pain, or lymphedema.

Conclusion: Psychosocial recovery is an **integral, medically recognized component** of post-mastectomy rehabilitation. By improving body-image stability and eliminating displacement anxiety, **L8031 fulfills Medicare's rehabilitative intent**and should be covered on parity with L8030.

Section 4: Legal & Regulatory Framework Summary

This section establishes the **legal foundation** for Medicare coverage of **HCPCS L8031** and documents how the **current LCD denial conflicts with federal law**.

A. Medicare Statutory Authority – Prosthetic Device Benefit

Social Security Act §1861(s)(8) defines a covered prosthetic device as:

"**Prosthetic devices which replace all or part of an internal body organ.**"

- HCPCS **L8031 replaces the surgically absent breast** following mastectomy
- Same benefit category already used by Medicare for **L8030**
- The **method of attachment does not change benefit eligibility**

B. Reasonable and Necessary Requirement

42 U.S.C. §1395y(a)(1)(A) states:

- "No payment may be made for any expenses for items or services that are not reasonable and necessary…"
- Medical literature **demonstrates necessity** in defined cases (bra intolerance, spinal compensation, pain reduction)
- **No federal rule allows denial based on suspension method differences**
- L8031 satisfies **Medicare's 3-part necessity test:**
    - Treats a diagnosed condition
    - Demonstrates clinical benefit
    - Appropriate for use in the home

C. LCD Evidence Requirement – 21st Century Cures Act

Section 4009 of the 21st Century Cures Act requires:

LCDs must include **"a summary of the evidence considered"** and be **transparent and publicly available.**

⚠ **LCD L33317 cites no evidence for denying L8031**
⚠ Current noncoverage statement violates **federal evidence transparency requirements**

D. CMS Program Integrity Manual Violation

Under **CMS Program Integrity Manual (PIM), Chapter 13**:

- LCDs must **"reflect the best available clinical evidence."**
- Coverage decisions must not be **arbitrary or unsupported**.

⚠ The statement **"no clinical advantage has been demonstrated"** is **unsupported and incorrect**

⚠ Peer-reviewed data **contradict the LCD**

E. CMS Health Equity Framework

The **CMS Framework for Health Equity (2022–2032)** requires removal of **coverage barriers that disproportionately burden specific populations**.

- Breast cancer survivors are a **high-priority CMS population**
- Current policy **creates sex-based inequity** and **barriers to survivorship care**
- Immediate correction is **consistent with federal equity policy**

Legal Conclusion

HCPCS **L8031 qualifies for Medicare coverage under federal law**. The current LCD denial:

- **Has no legal basis**
- **Is not evidence-based**
- **Violates CMS policy transparency**
- **Must be corrected via reconsideration**

Evidence Table – Adhesive External Breast Prostheses (L8031) After Mastectomy

#	Study (Year)	Design / N	Key Findings Relevant to L8031	Policy Relevance
1	Thijs-Boer, Thijs, van de Wiel (2001) – *Cancer Nursing*	Randomized crossover, n=101	59.3% preferred the adhesive prosthesis; users described it as feeling "part of the body" with improved comfort and security.	Demonstrates patient-important benefit and preference; rebuts "no advantage" argument.
2	Münstedt, Milch, Zygmunt (1998) – *Supportive Care in Cancer*	Prospective clinical trial, n=55, 6-month follow-up	90.7% would recommend adhesive forms; reported more natural movement and greater clothing options.	Shows functional + quality-of-life gains; supports reasonable and necessary status.

#	Study (Year)	Design / N	Key Findings Relevant to L8031	Policy Relevance
3	Münstedt et al. (1996) – *Geburtshilfe und Frauenheilkunde*	Observational clinic series	Adhesive prostheses rated more natural in weight and movement; improved confidence in social activity.	Demonstrates body integration and psychosocial benefits consistent with prosthetic use.
4	Qiu et al. (2020) – *Medicine (Baltimore)*	Randomized crossover, 12-week use	Adhesive attachment improved stability, reduced displacement, and increased willingness to continue use; cleaning was a minor trade-off.	Supports functional superiority and mobility benefit.
5	Hackethal et al. (2004) – *Breast Care*	Clinical/biomechanical review	Recommends weight-reduced, self-adhesive forms to reduce shoulder loading from bra straps.	Demonstrates biomechanical rationale for reducing musculoskeletal strain.
6	Qiu et al. (2021) – *Gland Surgery*	Cross-sectional provider survey	Clinicians identify adhesive external breast prostheses as improving comfort, aesthetics, and psychological well-being; indicated for bra intolerance.	Demonstrates broad clinical adoption and medical indications.
7	Kubon et al. (2012) – *J Multidisciplinary Healthcare*	Mixed-methods cohort	Patients reported comfort, aesthetics, and psychosocial benefits with modern EBPs; adhesive options preferred by many.	Supports quality-of-life and functional benefit recognized by Medicare prosthetic policy.
8	Fitch, McAndrew, Harth (2012) – *Canadian Oncology Nursing Journal*	Qualitative survivor interviews	Adhesive and other EBPs improve body image, social participation, and active living; cost/coverage were major access barriers.	Supports coverage parity—denial creates avoidable harm and inequity.

#	Study (Year)	Design / N	Key Findings Relevant to L8031	Policy Relevance
9	Jetha, Faustino, Davis (2017) – *Asia-Pacific Journal of Oncology Nursing*	Qualitative study	Users describe greater confidence, security, and reduced shifting anxiety with adhesive prostheses.	Confirms psychosocial and daily function medical benefit.
10	NCCN & ASCO Survivorship Guidelines	Clinical guidelines	Recommend offering external breast prostheses when reconstruction is not chosen or feasible.	Establishes medical—not cosmetic—necessity; supports parity with L8030.

Synthesis of Clinical Advantages Demonstrated Across Studies

- **Biomechanics:** Adhesive fixation **transfers load to the chest wall**, reducing **strap-borne trapezius/cervical strain** (Hackethal 2004).
- **Stability & Function: Less lateral shift/displacement** and **greater movement confidence** (Qiu 2020; Münstedt 1998).
- **Tolerance & Indications:** Appropriate for **bra intolerance**, **lymphedema**, **radiation fibrosis/chest-wall tenderness**, and **prosthesis instability** (Qiu 2021).
- **Patient-Reported Outcomes: Higher comfort**, **preference**, **natural feel**, **body-image restoration**, and **social reintegration** (Thijs-Boer 2001; Fitch 2012; Jetha 2017).
- **Guideline Consistency:** NCCN/ASCO survivorship guidance treats EBPs as **rehabilitative care**, not cosmetic.

Bottom line: The **published evidence directly contradicts** the LCD assertion that L8031 has "no demonstrated clinical advantage." Clinical and patient-important benefits are **repeatedly shown** across study types.

Section 5 – Legal Authority & Statutory Citations Supporting Coverage of HCPCS L8031

The request to provide full Medicare coverage for **HCPCS L8031 – External Breast Prosthesis, Silicone with Integral Adhesive** under **LCD L33317** is supported by the following federal laws, CMS policies, and regulatory requirements.

I. Social Security Act – Medicare Prosthetic Device Benefit

Legal Authority: SSA §1861(s)(8)
Text: *"Prosthetic devices which replace all or part of an internal body organ…"*
Relevance to L8031:

- The breast is recognized as an internal body structure.
- L8031 **replaces the surgically absent breast** following mastectomy.
- L8031 **meets identical benefit eligibility as L8030**, already covered by Medicare.
- **Method of suspension (adhesive vs. bra pocket) does not change benefit category classification.**

II. Medicare Coverage Requirement – Reasonable and Necessary Standard

Legal Authority: 42 U.S.C. §1395y(a)(1)(A)
Text: *"No payment may be made for any expenses incurred for items… which are not reasonable and necessary…"*
Relevance to L8031:

- Clinical studies demonstrate clear **functional and psychological health benefits**.
- L8031 is prescribed **to restore function, reduce pain, and improve quality of life**.
- These outcomes meet **Medicare's definition of reasonable and necessary**.

III. LCD Transparency Requirement – 21st Century Cures Act

Legal Authority: Section 4009, 21st Century Cures Act
Requirement: LCDs must **cite the evidence used to support coverage or noncoverage**.
Violation in Current LCD:

- LCD L33317 states **"no clinical advantage has been demonstrated"** for L8031.
- **Zero clinical citations** are provided to justify denial.
- This failure to cite evidence **violates federal LCD transparency standards**.

IV. CMS Program Integrity Manual Requirements

Authority: CMS Program Integrity Manual (PIM), Pub. 100-08, Chapter 13

- LCDs must be based on **"sound clinical evidence"**.
- Contractors may **not issue arbitrary coverage denials**.
  Relevance:
- **Evidence exists** for clinical advantage of adhesive prostheses (Appendix A).
- The current LCD statement is therefore **noncompliant with CMS PIM policy**.

V. CMS Medical Evidence Hierarchy

Authority: CMS Benefit Policy Manual §20.3

- Accepts **peer-reviewed literature** and **clinical standards** as valid evidence.
- **Multiple PubMed-indexed studies** support L8031 medical benefits.

- CMS must **consider available evidence** when reconsidering policies.

VI. CMS Health Equity Obligation

Authority: CMS Framework for Health Equity 2022–2032

- CMS must **advance equity in coverage policy**.
- Current LCD **disproportionately harms women** recovering from cancer.
- **Failure to cover L8031 is an access barrier** and violates CMS equity goals.

Conclusion – Legal Basis Established

Under **SSA §1861(s)(8)** and **42 U.S.C. §1395y(a)(1)(A)**, **HCPCS L8031 must be covered** as a prosthetic device.
The current LCD denial:

- **Has no medical evidence support**
- **Violates the Cures Act**
- **Conflicts with CMS policy manual requirements**
- **Causes inequitable harm to Medicare beneficiaries**

Legal standard for LCD reconsideration is clearly met.

Proposed LCD Revision Language

PROPOSED LCD LANGUAGE REVISION

LCD Title: L33317 – External Breast Prostheses
Proposed Revision: Remove HCPCS **L8031** from **Noncovered Items** and establish coverage as follows:

Add to Covered Indications Section:

HCPCS L8031 – External breast prosthesis, silicone or equal, with integral adhesive is **reasonable and necessary for beneficiaries who have undergone unilateral or bilateral mastectomy**for the purposes of **restoration of normal body configuration and equilibrium**. This item is covered under the **Medicare Prosthetic Device benefit** as described in **Section 1861(s)(8) of the Social Security Act**, as it **replaces the surgically absent breast** following mastectomy.

Coverage Criteria:

Coverage for **L8031** is considered medically necessary when **any** of the following criteria are met:

1. The beneficiary elects adhesive suspension instead of pocket-based suspension for improved function or comfort; **OR**
2. The beneficiary has **clinical need** for adhesive suspension, including but not limited to:
    - Post-mastectomy pain or scar sensitivity preventing tolerance of a compression/bra pocket prosthesis
    - Shoulder strain or cervical pain associated with strap-borne prosthetic weight
    - Lymphedema or lymphedema risk where bra compression is contraindicated
    - Prosthesis instability or displacement during normal activities
    - Dermatologic sensitivity or friction resulting from gravity-based prosthesis suspension

Documentation Requirements:

- Standard Written Order (SWO)
- Diagnosis of acquired absence of breast (ICD-10-CM Z90.10–Z90.13)
- Clinical documentation supporting prosthetic need
- Prosthetic evaluation notes from physician, prosthetist, or certified fitter

Utilization Parameters:

- Same frequency limitations apply as **L8030**: **one breast prosthesis per side every 24 months**
- Replacement allowed for documented **loss, damage, or medical necessity**
- Billing modifiers: **RT, LT** and **-KX** modifier **when criteria are met**

Remove from Current LCD:

Delete this incorrect statement from the Noncovered Section:
"A silicone breast prosthesis with integral adhesive (L8031) has not been demonstrated to have a clinical advantage… and is therefore **not reasonable and necessary**."

J**ustification:** This statement is **clinically obsolete and unsupported by medical evidence**, and its inclusion **violates the 21st Century Cures Act transparency requirement (Section 4009)**.

Proposed Revision to Local Coverage Article A52512

(Companion billing & coding article for LCD L33317 – External Breast Prostheses)
This section ensures that **HCPCS L8031 can actually be billed and paid correctly** by suppliers once coverage is restored.

PROPOSED CHANGE TO A52512 – External Breast Prosthesis Policy Article

Add the following under "Covered Codes":

L8031 – External breast prosthesis, silicone or equal, with integral adhesive
Covered when the beneficiary meets coverage criteria outlined in LCD **L33317**. Coverage is provided under the **Medicare prosthetic benefit (§1861(s)(8))** to replace the surgically absent breast following mastectomy.

Coding Guidance Update:

HCPCS Code	Description	Coverage Status
L8030	Breast prosthesis, silicone or equal	Covered

HCPCS Code	Description	Coverage Status
L8031	**Breast prosthesis, silicone or equal, with integral adhesive**	**Covered** *(Proposed)*
L8020	Breast prosthesis, foam	Covered
L8015	Mastectomy bra	Covered
A4280	Adhesive skin support (replacement supply)	Covered for L8031 users

Modifiers:

Suppliers must report:

- **RT** – Right side
- **LT** – Left side
- **KX** – Requirements specified in the medical policy have been met
- **GA/GZ** – Only if criteria not met or ABN obtained

Documentation Language to Add:

For L8031: Medical records must document **prosthetic need following mastectomy** and either **beneficiary preference** for adhesive suspension **or clinical necessity** due to bra intolerance, prosthesis instability, pain, or lymphedema.

Remove the Following From A52512:

DELETE: "L8031 is statutorily noncovered because it does not meet the definition of a prosthetic device."
*This is incorrect. L8031 meets the statutory definition under **SSA §1861(s)(8)** and is functionally equivalent to L8030.*

Peer-Reviewed Clinical References

Fitch, M. I., McAndrew, A., & Harth, T. (2012). Perspectives of women about external breast prostheses after mastectomy: Body image, activity, and satisfaction. *Canadian Oncology Nursing Journal, 22*(3), 166–174.

Hackethal, A., Sick, C., König, J., & Münstedt, K. (2004). Shoulder strain caused by mammary prostheses. *Breast Care, 1*(2), 122–126.

Jetha, Z. A., Fausto, R. S., & Davis, C. (2017). Women's experiences of using external breast prosthesis after mastectomy. *Asia-Pacific Journal of Oncology Nursing, 4*(4), 356–362.

Kubon, T., Baylis, B., & Aubertin, M. (2012). A mixed-methods cohort study to determine perceived patient benefit in providing custom breast prostheses. *Journal of Multidisciplinary Healthcare, 5*, 9–15.

Münstedt, K., Milch, W., & Zygmunt, M. (1998). Epicutaneous breast forms. A new system promises to improve body image after mastectomy. *Supportive Care in Cancer, 6*(5), 454–458.

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Qiu, J., Chen, W., Zhou, Q., Zhu, S., & Li, L. (2020). Physical and psychological effects of different temperature-controlled breast prostheses. *Medicine, 99*(13), e19509.

Qiu, J., Zhou, Q., Mao, Q., Ding, X., & Li, L. (2021). Medical professionals' knowledge of the use of external breast prostheses. *Gland Surgery, 10*(2), 623–632.

Thijs-Boer, F. M., Thijs, J. T., & van de Wiel, H. B. (2001). Conventional or adhesive external breast prosthesis? A prospective study of patients' preference after mastectomy. *Cancer Nursing, 24*(3), 227–230.

Regulatory & Medicare Policy Citations

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Centers for Medicare & Medicaid Services. (2023). *Medicare Benefit Policy Manual (Pub. 100-02), Chapter 15, §120 – Prosthetic Devices*.
National Comprehensive Cancer Network. (2023). *NCCN Guidelines for Survivorship*.
U.S. Congress. (2016). *21st Century Cures Act, §4009 – Transparency in Local Coverage Determinations*.
42 U.S.C. §1395y(a)(1)(A).
Social Security Act §1861(s)(8).

U.S. Food and Drug Administration. (2024). *Product Classification – External Breast Prosthesis (Prosthetic Breast Form)*. Product Code **"ILF"** – **Medical Device, Class II** (special controls), **Regulated as a prescription prosthetic medical device**.
Retrieved from: https://www.accessdata.fda.gov **(FDA Device Database)**

Relevance: Confirms that external breast prostheses, including **adhesive types**, are recognized as **prosthetic medical devices** under federal law — not cosmetic enhancements.