



vive
health

Quality
November 2025

Vive's Quality Team



Colombia



Carolina Silva

Quality Analyst

Analyzes trends and manages injury case form submission.

Biomedical Engineer w/ Data Analytics skill set



Luis Hidalgo*

Customer Service

Troubleshooting Specialist

Assists and trains support agents - supports Carolina's report and analysis projects.

Biomedical Engineer.



China



Annie

QC Manager in China

Contracts inspectors across China - manages inspection reports and reviews data.

- ~25 QC Inspectors, China



Jason

QC at MPF

Leads MPF inspection team, inspects and troubleshoots to ensure highest quality.

- ~7 QC Inspectors, MPF



US / UK



Jim Ahearn

Research and Testing

Leads product testing at Naples Office - Retired PhD Chemist.



Jessica Marshall

US - by way of the UK;

Regulatory Affairs & Compliance

Leads our ISO 13485 initiative, EU and LATAM market access.

Physical Therapist with RA experience

*Not directly assigned to quality, but significantly helps our team reduce returns and increase customer satisfaction

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Agenda

Today's Agenda

Why we do what we do



Strategic Value

Our "Why": Quality as a market differentiator and revenue generator.

How we are doing



Performance Review

The "What": A data-driven look at our core metrics and trends.

What we are doing



Process & Proactivity

The "How": Our systems for finding, fixing, and preventing issues.

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Wins

Quality as a Revenue Generator

Expanding markets and building new value.

Returns Performance

Internal Awareness

🌐 Market Expansion

CE Mark (Est. Nov 2025) & ISO 13485 will more than **double our TAM** by unlocking the EU (+450m people) & UK (+70m), accessing a **+\$150B device market**.

\$ Direct Revenue

We developed our own **memory foam seat cushion** to generate revenue, offset costs, and gain deep insight into the full product development process.

📊 AI-Driven Efficiency

Using Gemini & Claude ("Vibe Coding"), we build custom web apps for analysis. This provides a **tremendous ROI** with no special tools or budget.



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GLOBAL MARKET EXPANSION

New CE Mark Unlocks Significant Growth



Why CE?

Increased TAM: CE is the requirement to access a market larger than the US!

153%
INCREASE IN
MARKET REACH

75%
INCREASE IN
MARKET VALUE

~\$150B

Total Medical Device Market

**\$22B –
\$37B**

Our Class I Equivalent
Market

- Total EU & UK Market Size of Class I Equivalent Med Devices is \$22B to \$37B.
- US Med Device Market Size est. at +\$200B, class I size unknown.
- 153% Increased TAM based on population size of new markets compared to US.
- Total TAM increase % based on USD \$s is +75%.

Google. (2025, November 20). Gemini [Deep research market analysis of Class I medical device market size]

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How We Integrate Quality

Customer Satisfaction

Returns Performance

Internal Awareness

Proactive Involvement



Concept & Development

We provide critical upfront analysis of the competitive and regulatory landscape, establishing the DHF, risk analysis, and testing protocols.

Active Monitoring & Decisions



Manufacturing & Launch

We ensure supplier readiness through factory audits, confirm product integrity with V&V testing, and oversee initial production for a smooth launch.

Lifecycle Management



Post-Market & Improvement

We capture and analyze all post-launch customer data to monitor performance, perform Root Cause Analysis, and drive continuous improvement.

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Performance

August 2025

Key Goal Performance

A detailed look at our core metrics.

Customer Satisfaction

Returns Performance

Internal Awareness

VoC Listing Health

Higher is better

On Track

82.16% / 85% Target

97% of Goal

B2B Return Rate

Lower is better

Needs Focus

2.20% / 2.00% Target

90% of Goal

August 2025

FBA Return Rate

Lower is better

Exceeding

7.46% / 7.50% Target

100.5% of Goal

ISO 13485 Implementation

Higher is better

On Track

30% / 100% Target

30% of Goal

Performance November 2025

Key Goal Performance

A detailed look at our core metrics. (Data: Nov 2025)

Customer Satisfaction

Returns Performance

Internal Awareness

VoC Listing Health

Higher is better

On Track

77.61% / 85% Target

A horizontal progress bar consisting of a yellow segment followed by a grey segment.

91.3% of Goal

FBA Return Rate

Lower is better

Exceeding

5.54% / 7.50% Target

*As of 11/7/2025 - 6.51% on 11/10/2025

A horizontal progress bar consisting of a blue segment.

126.13% of Goal

B2B Return Rate

Lower is better

Needs Focus

2.29% / 2.00% Target

A horizontal progress bar consisting of a red segment followed by a grey segment.

85.5% of Goal

ISO 13485 Implementation

Higher is better

On Track

42.5% / 100% Target

A horizontal progress bar consisting of a yellow segment followed by a grey segment.

42.5% of Goal

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Performance

Amazon Listing Health Categorization – NCX Rate

Customer Satisfaction

- **One Team Communication:** We drive a constant, proactive feedback loop across all departments—from leadership to the warehouse floor—to ensure alignment and rapid response.
- **Proactive Problem-Solving Loop:**
 - **Find (Situation):** We dedicate time to proactively identify issues, like a small spike in the return rate for a specific product.
 - **Fix (Task & Action):** A cross-functional team brainstorms and analyzes data (e.g., "doesn't fit" or "not durable"). Actions include full sizing analysis against competitors or research into new, pre-tested materials.
 - **Follow-Up (Result):** We implement the data-backed change (new sizing, new materials) and measure post-launch performance to confirm the fix was successful.
- **Accountability & Tracking:** All action items are documented, assigned, and tracked via Smartsheet from discovery to resolution.

Percent of Amazon Listings with "Good or Excellent" NCX categorization

Higher is better

77.61% / 85% Target

On Track

91.3% of Goal



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Explaining the Voice of the Customer (VoC)

How Amazon translates feedback and market data into our performance rating.

Amazon Voice of the Customer (VoC)

Customer Satisfaction

Percent of Amazon Listings with "Good or Excellent" NCX categorization

Higher is better

77.61% / 85% Target

On Track

91.3% of Goal

Negative Customer Experience
(NCX)

Amazon Channel Competitiveness

$(1\&2 \text{ Star Reviews} + \text{Product Returns}) / \text{Total Orders}$

Reviews

Return Rates



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Performance

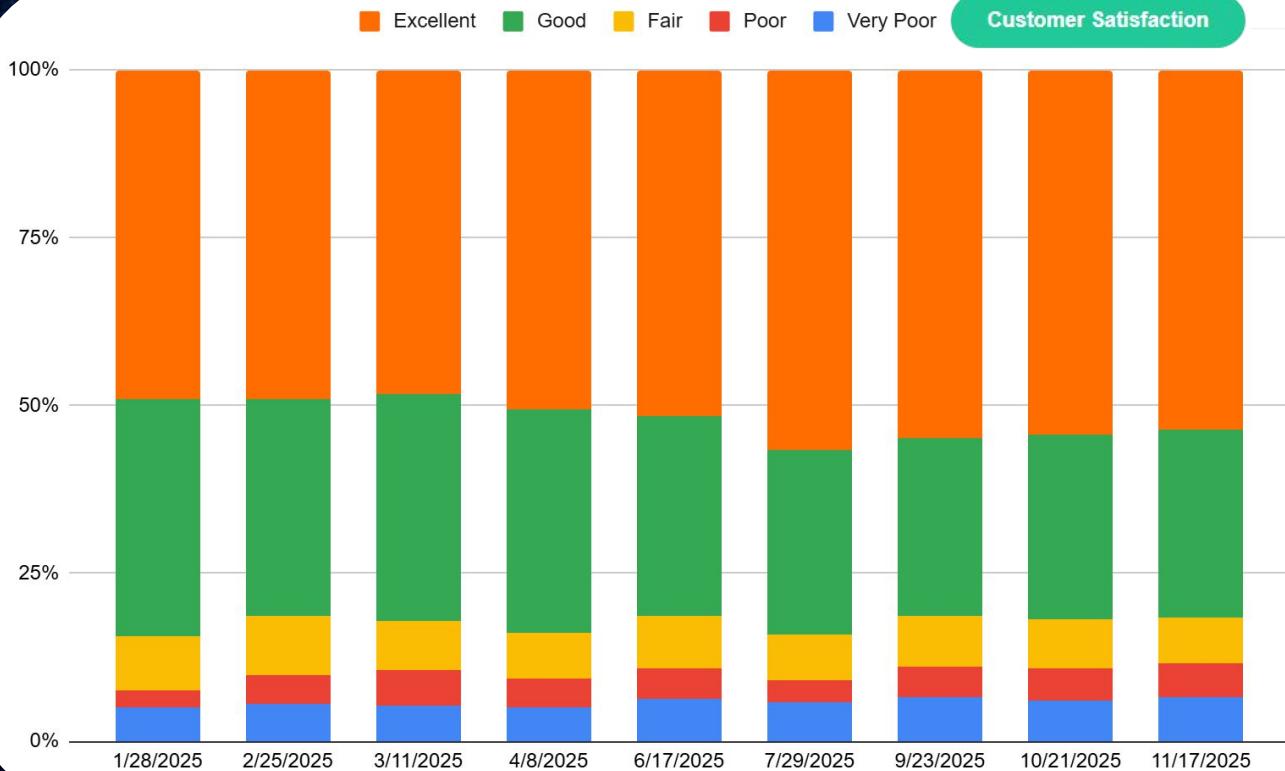
Amazon Listing Health Categorization - NCX Rate

Percent of Amazon Listings with "Good or Excellent" NCX categorization
Higher is better

On Track

77.61% / 85% Target

91.3% of Goal



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Returns Performance

Case Study: Post-Op Shoes

- Situation:** This category has an extremely high return rate (20-40%) due to "fit" and "size" complaints, which many accept as the status quo.
- Task:** Challenge the status quo and find a data-driven way to improve, even marginally.
- Action:** We are investing hours in deep analysis: ordering/measuring competitor samples, studying foot measurement guides, and reviewing size charts.
- Result (Ongoing):** Key finding so far: Our shoes are 5-11% larger than the top market brand. This project shows our commitment to data-driven, continuous improvement.

FBA Return Rate
Lower is better

Exceeding

5.54% / 7.50% Target

126.13% of Goal

Performance

FBA Return Rate Reduction

Returns Performance

Last 90 days Marketplace Product Group
United States All Product Group

Graph is showing your return rates and return units from August 2025 - November 2025. Last updated on November 4, 2025.

Average Return Rate
7.39 %

Total Return Units
38507 Units

Number of ASINs with Returns
1146 ASINs

FBA Return Rate
Lower is better

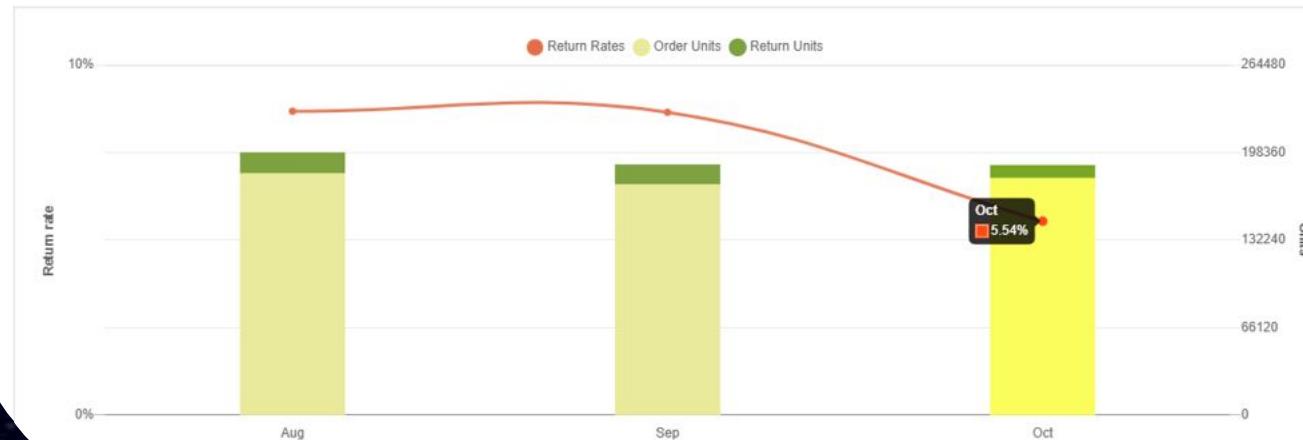
5.54% / 7.50% Target

Exceeding

126.13% of Goal

Returns Performance

5.45% 11/06/2025



Summary of Returns

Post Op Shoe (Large)

Top Return ASIN

B00ZNU6JRK

Top Customer Reported
Return Reason

"Size too
large/long"

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Performance

FBA Return Rate Reduction

Returns Performance

Date Marketplace Product Group

Graph is showing your return rates and return units from August 2025 - November 2025. Last updated on November 16, 2025.

Average Return Rate

7.41 %

Total Return Units

39048 Units

Number of ASINs with Returns

1155 ASINs

FBA Return Rate

Lower is better

5.54% / 7.50% Target

Exceeding

126.13% of Goal

Returns Performance

7.4%
11/17/2025



Summary of Returns

Shoe Lift Balancer Large

Top Return ASIN

BOFHS4812S

Top Customer Reported
Return Reason

"Size too
large/long"

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Returns Performance

Systemic Improvements

- **Cross-Department Collaboration:** Working directly with department leaders on product development and customer support.
- **Formal Stakeholder Sign-Offs:** A new process to ensure all requirements are met before launch, preventing costly misalignments.
- **Pre-Production Feedback:** Getting feedback from trusted customers *before* full production begins to catch issues at the earliest stage.
- **Closer Communication Loops:** More frequent and focused channels to keep all teams aligned on product changes and goals.

B2B Return Rate

Lower is better

2.29% / 2.00% Target

Needs Focus

85.5% of Goal

Company-Wide Return Rate

Returns Performance

Return Rate → Projected Rate % (Poly)

15%

14%

13%

12%

11%

10%

9%

8%

$R^2 = 0.1484$

</= 7% Target

7%

6%

5%

4%

3%

2%

1%

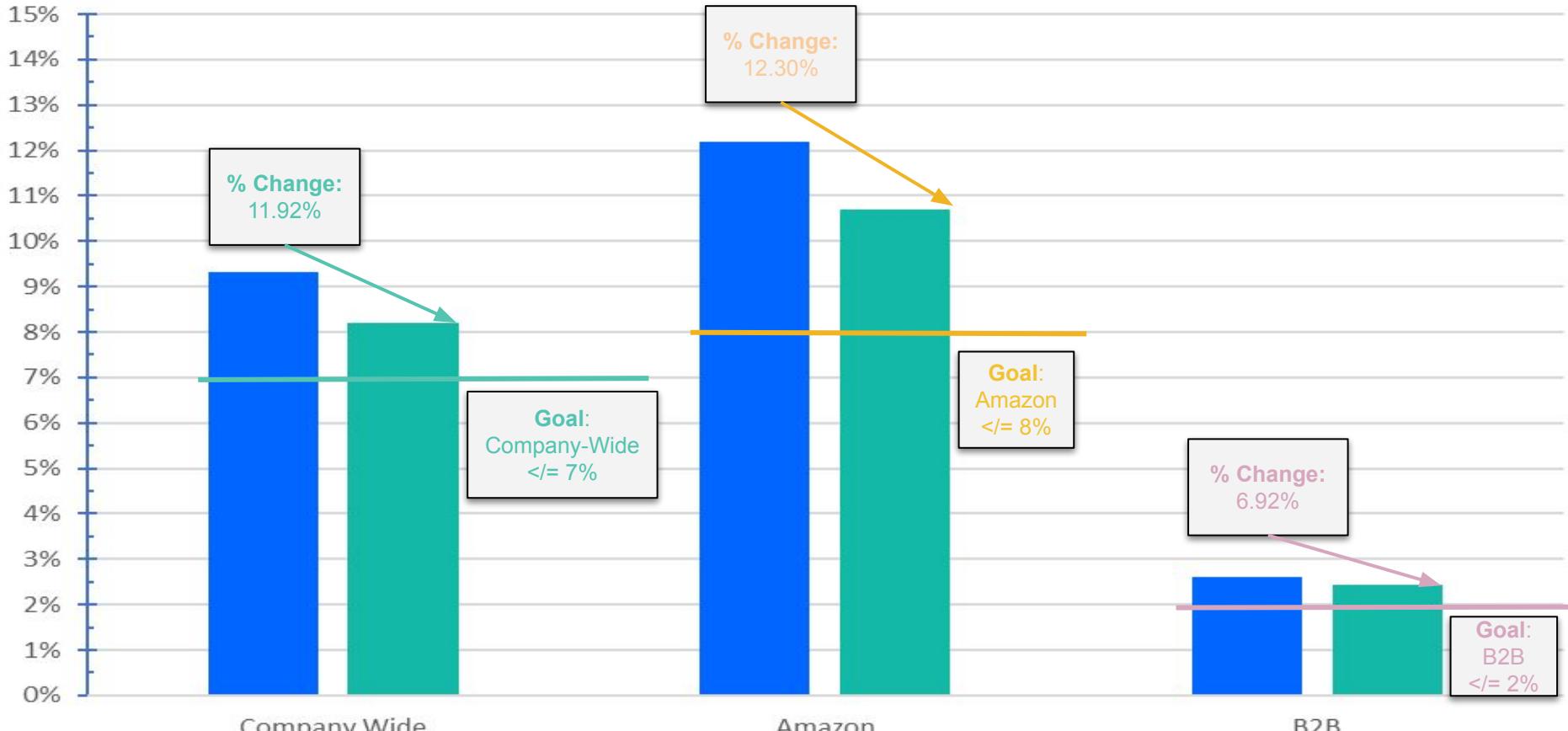
0%

Data Source: Vive Health P&L, 11/10/2025

Apr 2024 May 2024 Jun 2024 Jul 2024 Aug 2024 Sep 2024 Oct 2024 Nov 2024 Dec 2024 Jan 2025 Feb 2025 Mar 2025 Apr 2025 May 2025 Jun-25 Jul-25 Aug-25 Sep-25 Oct-25

Company-Wide Return Rate & by Major Channels

Returns Performance



Performance

Actions Taken

Customer Satisfaction

Returns Performance

Internal Awareness

The Problem

Costly mistakes were made where changes benefiting one department (e.g., changing packaging to optimize FBA fees) negatively impacted another (e.g., B2B sales channel).

The Solution

Product, Quality, and Sales leadership agreed to improve collaboration through data, transparency, and formal sign-offs. Decisions are now driven by holistic data (e.g., contribution margins vs. total volume).

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Internal Awareness

Making our own products saves money, but it comes with risks. We are using communication and sign-offs to make better decisions, together. No blaming.

-  **Phased Rollouts:** When possible, we will keep existing inventory in stock during a new product transition to avoid stock-outs (e.g., OA knee brace lessons).
-  **Pre-Production Feedback:** We will air-ship new products to trusted customers for feedback *before* full production begins.
-  **Agile Inventory:** We will use smaller initial order sizes (JIT inventory) even after initial feedback is received to remain flexible.

Customer Satisfaction

Returns Performance

Data and Systems Driven

We leverage data analytics at every level of our department. By creating our own custom tools and reports, we transform raw information into targeted, actionable improvements that have a real-world impact.

Example in Action: Sizing Analysis

Our custom dashboards identified a high volume of returns due to "too small" or "too large" reasons. This data allowed us to pinpoint specific products and work with the Product team to review sizing guides and manufacturing specs, directly addressing a key driver of dissatisfaction.

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Overcoming Challenges

Cost Savings

In-House Tool Saves ~40hrs/Month

This is a real example of an in-house tool built by our team. It uses AI to categorize thousands of customer return comments, saving dozens of manual-review hours per month.

Key Features:

- Preserves exact file format & only modifies Column K
- Handles 2,600+ rows efficiently
- 100% AI categorization accuracy
- Google Sheets compatible export

Internal Awareness



Zero Dedicated Software Budget

All tracking and analysis were performed without purchasing external quality dashboards. We leverage existing tools to maximize value.



Leveraging Cross-Departmental Tools

We partner with eComm, Sales, and Product to utilize their existing reports and data, adapting them for our quality analysis and goals.



Building Our Own Solutions (High ROI)

Using our Gemini & Claude subscriptions ("Vibe Coding"), we build our own custom web apps for analysis. This provides a tremendous ROI for a minimal cost.

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Overcoming Challenges

E.g., In-house built AI tool saves ~40hrs/month

Customer Satisfaction

Returns Performance

Internal Awareness

The screenshot shows a web-based application for managing return data. On the left, there's a sidebar with sections for Configuration (AI Provider set to Fastest (Claude Haiku)), Performance Settings (Processing Chunk Size: 100 rows, API Batch Size: 25), Display Options (Show Product/SKU Analysis checked), and Session Statistics (Total Cost: \$0.000). The main area has a teal header bar with status: Handles 2600+ rows, Column K export, Google Sheets Compatible. Below it, a dark panel shows Available AI: OpenAI, Claude. A central box titled "Upload Return Data File" displays current setup: Complaints from Column I → AI Categories to Column K. It includes sections for File Format & Instructions, Required File Structure (Column I: Complaint/Investigation Text required, Column B: Product identifier/SKU optional, Column K: Will receive AI categories auto-created), Supported Formats (Excel files (.xlsx, .xls), CSV files (.csv), FBA Return Reports (.txt)), Key Features (Preserves your exact file format, Only modifies Column K, Handles 2600+ rows efficiently, Google Sheets compatible export, 100% AI categorization accuracy, Real-time progress tracking), and a note about file structure: Complaints in Column I + Categories added to Column K. At the bottom, there's a "Choose file" button, a "Drag and drop file here" area with a 200MB limit, a "Browse" button, and a "Manage app" link.



Customer Satisfaction

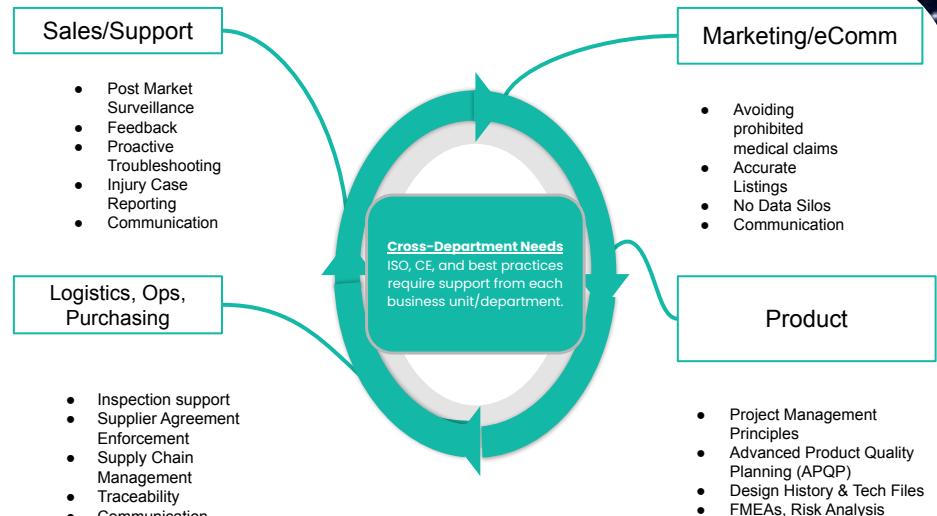
Returns Performance

Internal Awareness

Quality is a Team Sport

ISO, CE, and best practices require support from every business unit. Our success depends on aligned communication and shared goals.

- **Sales/Support:** Feedback loops, post-market surveillance, injury reporting.
- **Logistics/Ops:** Inspection support, traceability, supply chain management.
- **Marketing/eComm:** Avoiding prohibited medical claims, ensuring accurate listings.
- **Product:** Project Management, APQP, Design History Files, FMEAs, Risk Analysis.



Wins

Customer Satisfaction

Returns Performance

Internal Awareness



Saved \$570k+ in projected annual savings;

led return reduction, FBA fee optimization & inventory rework initiatives

*Includes savings from defective inventory rework, packaging changes, return rate reduction.
Doesn't account for process improvements and other harder to measure changes.*



Commanded market expansion;

executed 42.5% of ISO 13485 plan & secured CE Mark submission for +\$150B TAM

Class I market size estimated to be: \$22B - \$37B USD



Slashed FBA return rate to 5.54% (Oct);

drove B2B returns to 2.29%, strengthening all partner channels

FBA: Down 36% from August B2B: Down 11% from August



Orchestrated rework of 22.5k units;

salvaged \$250k in defective inventory & avoided total product loss

In Progress, pending shipping units back to China. Successful testing/proof of concept so far.



Managed 460+ quality tickets YTD;

maintained 45hr avg resolution & handled 150+ eComm/B2B requests

Not possible without significant help from our team and other department coordination.



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Review

A long time ago. In a company
far, far away

**PROACTIVITY
PERFORMANCE
CHALLENGES
STRATEGY
PHILOSOPHY
NEEDS**



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Questions or
Feedback?

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**STOP - Slides After this are
not to be presented**

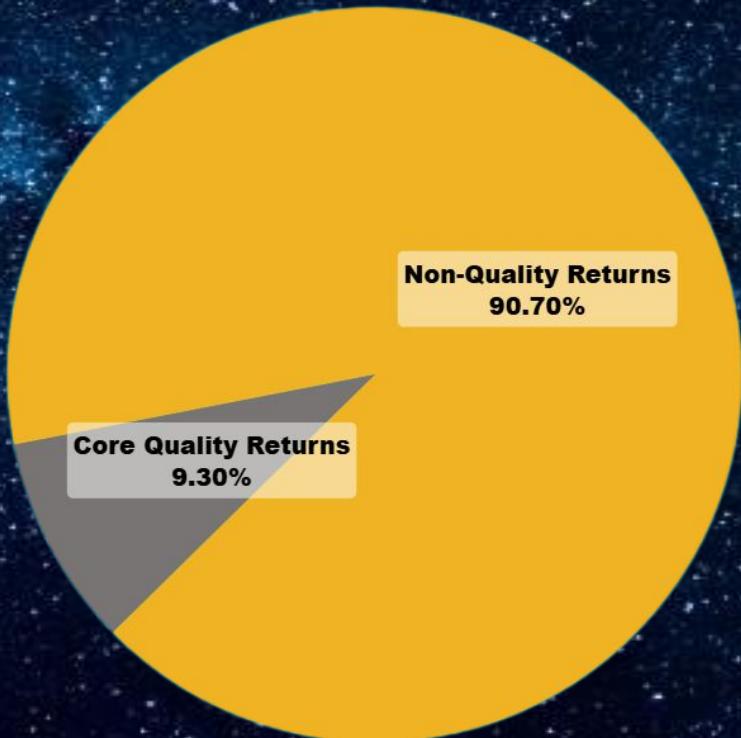
Performance

Amazon Return Reasons

Less than 1 out of 10 returns are due to Quality Issues

Customer Satisfaction

Returns Performance

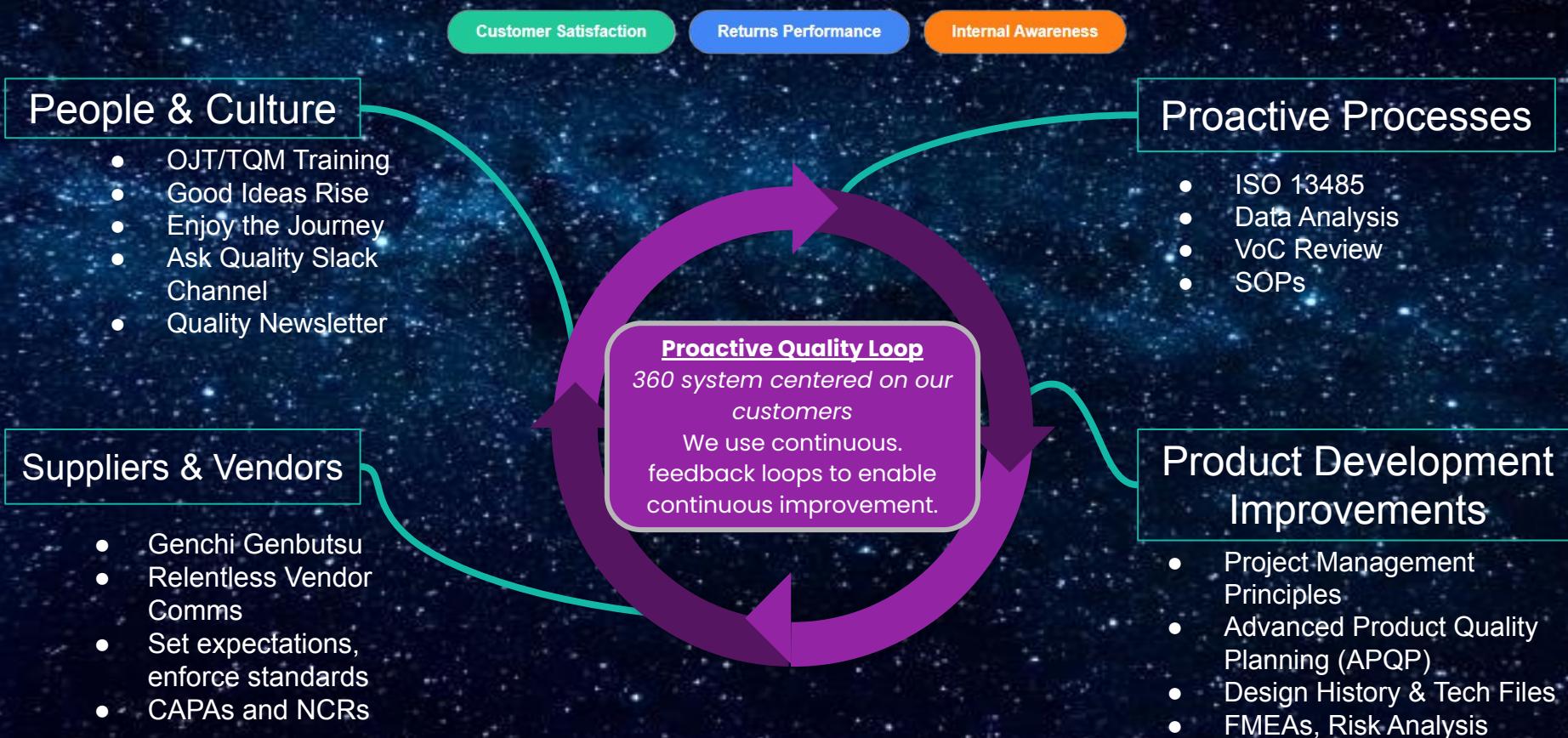


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Source: Amazon Return Report, YTD 2025 - 09292025

Strategy & Philosophy

360 Approach – Quality Loop



Strategy & Philosophy

Problem Assessment Matrix

Customer Satisfaction

Returns Performance

Internal Awareness

HIGH

HIGH

Severity of Impact

Frequency

I. Critical (1st Priority)

- High Impact
- High Frequency
- High Cost

Investigate First, issues in this category need to be solved quickly.

II. Important (2nd Priority)

- High Impact
- High Frequency
- Low Cost

Consider reviewing quickly as proactive measure before costs rise. *Safety risk correlates with cost and reg. reqs.*

III. Costly (3rd Priority)

- High Cost
- Low Frequency
- Low Severity

Explore cost saving and issue resolution.
Prioritize if cost is exorbitant.

VI. Low Priority (4th Priority)

- Low Impact
- Low Cost
- Low Frequency

Delegate or track for escalation to higher priority quadrants.

LOW

HIGH

Cost

LOW

Needs

ISO, CE, and Documentation Support

Sales/Support

- Post Market Surveillance
- Feedback
- Proactive Troubleshooting
- Injury Case Reporting
- Communication

Logistics, Ops, Purchasing

- Inspection support
- Supplier Agreement Enforcement
- Supply Chain Management
- Traceability
- Communication

Marketing/eComm

- Avoiding prohibited medical claims
- Accurate Listings
- No Data Silos
- Communication

Product

- Project Management Principles
- Advanced Product Quality Planning (APQP)
- Design History & Tech Files
- FMEAs, Risk Analysis
- Communication

Cross-Department Needs

ISO, CE, and best practices require support from each business unit/department.

Proactivity

Continuous Improvements

Quality Control

Processes which
Detect Defects

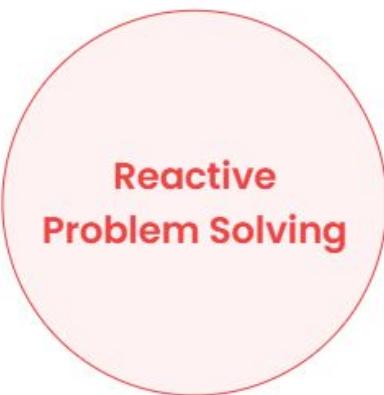
Quality Assurance

Processes which
Prevent Defects

Customer Satisfaction

Returns Performance

Internal Awareness



Quality Assurance Forward Approach

- ✓ Reduces risk before products reach customers.
- ✓ Reduces time and resources spent solving problems.
- ✓ Shifts our entire mindset from reactive to proactive.
- ✓ Aligns with our goals to catch problems during development, not after launch.

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Targeting Our Niche in the EU & UK Markets

Internal Awareness



Google. (2025, November 20). Gemini [Deep research market analysis of Class I medical device market size]

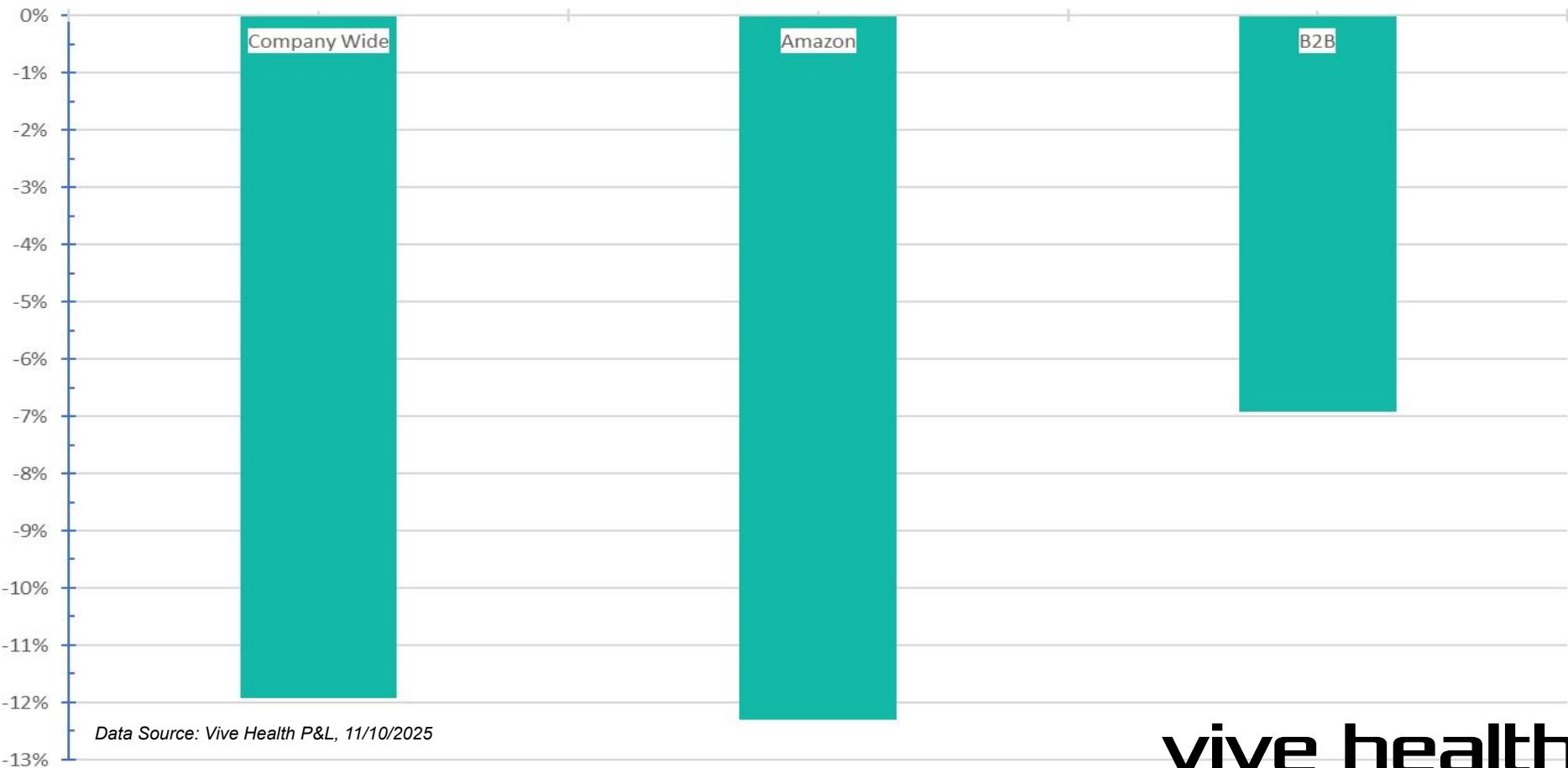
While the total market is vast, our Class I focus targets a highly valuable \$22B to \$37B segment.

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% Change Aug-25 to Oct-25

Returns Performance

■ % Change



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Closing

Internal Awareness

"Most Business Processes Are 90% Waste and 10% Value-Added Work."

— Jeffrey K. Liker

"TPS starts with the customer. Always ask, "What value are we adding from the customer's perspective?"'

— Jeffrey K. Liker

"The Toyota style is not to create results by working hard... People don't go to Toyota to 'work' they go there to 'think'."

— Taiichi Ohno

"Standardization Is the Basis for Continuous Improvement and Quality."

— Jeffrey K. Liker

"The most important factors for success are... an unforgiving commitment to quality."

— Robert B. McCurry

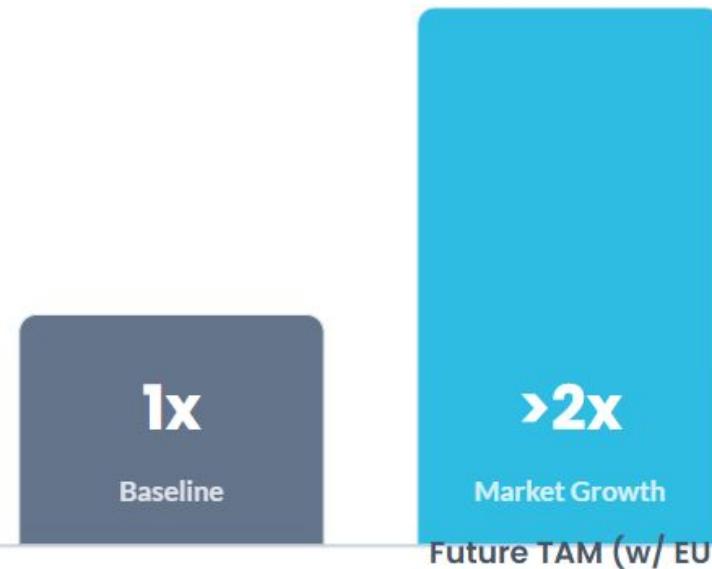
"Where there is no standard there can be no Kaizen."

— Taiichi Ohno

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Wins

Internal Awareness



Current TAM & UK
New market access represents a more than 100% increase in our Total Addressable Market.

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Non-Quality Related Returns

- APPAREL_STYLE
- APPAREL_TOO_LARGE
- APPAREL_TOO_SMALL
- DAMAGED_BY_CARRIER
- DAMAGED_BY_FC
- DID_NOT_LIKE_COLOR
- DID_NOT_LIKE_FABRIC
- EXCESSIVE_INSTALLATION
- EXTRA_ITEM
- FOUND_BETTER_PRICE
- MISORDERED
- MISSED_ESTIMATE
- MISSED_ESTIMATED_DELIVERY

*These may still be actionable areas of improvement.
However, they don't speak directly to a quality issue.*

Core Quality Returns

- DEFECTIVE
- QUALITY_UNACCEPTABLE
- MISSING_PARTS

Customer Satisfaction

Returns Performance

Strategy

CE TAM Increase

Internal Awareness

European Union

Action: Obtaining CE Marks

\$149 Billion
Market Size

450 Million+
People

Market size shown for comparison, CE is not required for LATAM. But ISO is strongly encouraged and required for certain devices.

Relative Market Size Opportunity (\$USD Billions)

European Union

\$149B

Mexico

\$7.5B

Colombia

\$2.5B

Why CE

Increased TAM: CE is the requirement to access a market larger than the US!

Mexico

\$7.5B Market

130M People

Colombia

\$2.5B Market

53M People