Xenex — FDA De Novo Story

(Clarifying the category for whole-room UV robots)

Case Study

Problem

COVID-era UV products created inconsistent claims and uneven testing. Hospitals lacked a clear regulatory category for evaluating whole-room UV robots.

Plan

Align early with Clinical and Legal. Build a claims-tight narrative grounded in evidence. Package messaging and assets to support the De Novo submission and make complex concepts easy for buying teams to understand.

Outcome

FDA granted De Novo to Xenex LightStrike+ (DEN230007; 09/01/2023), establishing the device classification “whole room microbial reduction device” (21 CFR 880.6510; product code QXJ).

The decision provided a clearer path for hospitals to compare authorized devices and understand how claims are evaluated within this category.

Why it matters

Helps stakeholders navigate a previously unclear space by making category boundaries, testing context, and device distinctions easier to interpret.

What shipped

Message house • claims grid • explainer video • one-pager • sales deck refresh • landing/social variants • internal briefing FAQ

My role

Strategy • scripting • creative direction • hands-on production • hook/caption/cut testing • cross-functional alignment with Sales, Product, Clinical, and Legal to keep claims simple, accurate, and defensible