

K220318 PAL Infiltration SystemOct 14, 2022
253 days to decisionK220318 · Product code: **QPB** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k220318/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Suction, Lipoplasty For Removal (QPB)
Date received	Feb 3, 2022
Decision date	Oct 14, 2022
Days to decision	253 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Microaire Surgical Instruments, LLC
Location	Chesterfield, VA, US
Contact	Glenn Gerstenfeld
Website	https://www.microaire.com
510(k) history	9 submissions · 9 cleared · 2012-2025

Microaire Surgical Instruments, LLC designs and manufactures surgical devices for General & Plastic Surgery and related specialties. The company operates with a manufacturing facility in Chesterfield, US, and serves surgeons globally through an established distribution network. Microaire has received FDA 510(k) clearances from total submissions since 2012. General & Plastic Surgery devices represent the dominant focus, accounting for 78% of regulatory submissions. The company remains active, with its most recent clearance in 2025. The company's product portfolio centers o...