

K782002 TRACH-COLLARDec 15, 1978
11 days to decisionK782002 · Product code: **EQN** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k782002/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laryngoscope, Nasopharyngoscope (EQN)
Date received	Dec 4, 1978
Decision date	Dec 15, 1978
Days to decision	11 days
Third-party review	No

APPLICANT

Company	Kinetic Concepts, Inc.
Location	Mchenry, IL, US
Website	http://www.kci-medical.com
510(k) history	48 submissions · 48 cleared · 1978-2005

Kinetic Concepts, Inc. was a global medical technology corporation specializing in wound care and negative pressure wound therapy solutions. Headquartered in San Antonio, Texas, the company developed foundational technologies for wound healing and operated in more than 25 countries. The company received FDA 510(k) clearances from total submissions between 1978 and 2005. Its regulatory portfolio focused primarily on General & Plastic Surgery devices, with notable clearances in wound closure and negative pressure therapy systems. This represents a strong historical track re...
