FDA 510(k) Premarket Notification

K012310 MODIFICATION TO:HL168D BLOOD PRESSURE MONITOR

CLEARED

Aug 22, 2001
30 days to decision

K012310 · Product code: **DXN** · Cardiovascular
Source: https://www.510kdatabase.net/k012310/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Jul 23, 2001
Decision date	Aug 22, 2001
Days to decision	30 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Health & Life Co., Ltd.**
Location	Taipei Hsien, TW
Contact	SUSAN CHEN
510(k) history	60 submissions · 60 cleared · 1999-2021