FDA 510(k) Premarket Notification

K233729 Ringer perfusion balloon catheter, 2.00 x 20mm (5881)

CLEARED

May 31, 2024
192 days to decision

K233729 · Product code: **LOX** · Cardiovascular
Source: https://www.510kdatabase.net/k233729/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheters, Transluminal Coronary Angioplasty, Percutaneous (LOX)
Date received	Nov 21, 2023
Decision date	May 31, 2024
Days to decision	192 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Ringer perfusion balloon catheter, 2.50 x 20mm (5882); Ringer perfusion balloon catheter, 2.50 x 30mm (5883); Ringer perfusion balloon catheter, 3.00 x 20mm (5884); Ringer perfusion balloon catheter, 3.00 x 30mm (5885); Ringer perfusion balloon catheter, 3.50 x 20mm (5886); Ringer perfusion balloon catheter, 3.50 x 30mm (5887); Ringer perfusion balloon catheter, 4.00 x 20mm (5888); Ringer perfusion balloon catheter, 4.00 x 30mm (58

APPLICANT

Company	**Vascular Solutions, LLC**
Location	Maple Grove, MN, US
Contact	Becky Astrup
Website	http://vasc.com/
510(k) history	11 submissions · 11 cleared · 2019-2024

Vascular Solutions, LLC is an interventional medical device company now part of Teleflex. The company specializes in cardiovascular devices for coronary and peripheral interventions, structural heart procedures, and mechanical circulatory support. Vascular Solutions operates with a manufacturing facility in Maple Grove, Minnesota. The company has received FDA 510(k) clearances from total submissions since its first clearance in 2019. Cardiovascular devices represent 91% of its regulatory submissions. The latest clearance was in 2024, demonstrating continued product innova...

CLINICAL EVIDENCE - NCT04862689

Investigation of the Ringer Perfusion Balloon Catheter (Ringer PTCA)

Status	Completed - *No results published to ClinicalTrials.gov*
Enrollment	60 patients (actual)
Study sites	7 sites
Condition studied	Coronary Stenosis
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Jun 30, 2023
Sponsor	Vascular Solutions LLC (Industry)

Primary outcome

Effectiveness of device success in dilatation/pre-dilatation of coronary stenosis during PCI.

Secondary outcome

Successful PCI