FDA 510(k) Premarket Notification

CLEARED

K222972 BioProtect Balloon Implant™ System

Aug 25, 2023
332 days to decision

K222972 · Product code: **OVB** · Radiology
Source: https://www.510kdatabase.net/k222972/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hydrogel Spacer (OVB)
Date received	Sep 27, 2022
Decision date	Aug 25, 2023
Days to decision	332 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Bioprotect, Ltd.**
Location	Tzur Yigal, IL
Contact	Itay Barnea
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells US LLP**
Contact	Janice Hogan

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

CLINICAL EVIDENCE - NCT00918229

Pilot Study to Assess the Safety and Efficacy of BioProtect Balloon in Prostate Cancer Subjects

Status	Completed
Enrollment	24 patients (actual)
Study sites	1 site
Condition studied	Prostate Cancer
Primary purpose	Prevention
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	May 1, 2011
Sponsor	BioProtect (Industry)

Primary outcome

Proportion of Subjects Achieving a Reduction of at Least 25% of the Volume of the Rectum Receiving at Least 70 Gy.

Secondary outcome

Rate of Occurrence of Grade 2 or Greater Rectal Adverse Event or Procedure Related Adverse Events.

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT00918229