

K180478 RectalPro 75 Endorectal BalloonNov 13, 2018
264 days to decisionK180478 · Product code: **PCT** · Radiology
Source: <https://www.510kdatabase.net/k180478/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Prostate Immobilizer Rectal Balloon (PCT) |
| Date received | Feb 22, 2018 |
| Decision date | Nov 13, 2018 |
| Days to decision | 264 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Qlrad International , Ltd. |
| Location | Almere, NL |
| Contact | Arjen Winkel |
| 510(k) history | 1 submissions · 1 cleared · 2018-2018 |

REGULATORY CONSULTANT

| | |
|-----------------|--------------------------------------|
| Consulting firm | Emergo Global Consulting, LLC |
| Contact | Audrey Swearingen |

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

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