



Comment from <i>Insert your name, title and affiliation</i>	Page number <i>Insert 'general' if your comment relates to the whole document</i>	Line/ section number	Comment and suggestion for rewording <i>Please insert each new comment in a new row.</i>	Character of comment • 'major' ^a =1 • 'minor' ^b = 2 • 'linguistic' ^c =3 <i>Please indicate your choice by writing the according number in this field, e.g. for major choose "1".</i>	Author's reply
Dr. Bonariol	General		The report is well-structured, I have no comments.	2	Thank you.
Summary					
-					
Description and technical characteristics of the technology					
Intuitive Surgical	35	374	<p>We would revise the description of Intuitive Surgical: da Vinci Surgical System as follows to be factually accurate:</p> <p><i>Intuitive Surgical: da Vinci® Surgical System:</i></p> <p>Intuitive Surgical, an American corporation and market leader in surgical robots was founded in 1995 and has launched four generations of robotic surgical systems. The current generation includes: da Vinci® Xi, SP, and X.</p> <ul style="list-style-type: none"> • The da Vinci® Xi system has four robotic arms. The system includes the most advanced instrumentation, vision, and features such as integrated table motion. The Xi is used for a variety of complex procedures. • The da Vinci® X has the same arm architecture as the Xi, but takes advantage of a number of cost-conscious options that reduce the overall price of the system. • The da Vinci® SP is designed specifically for single-port accesses. Three multi-jointed instruments and a 3DHD camera are all delivered through a single arm. 	1	Thank you. We revised the description as suggested.

Please add extra rows as needed.

¹ a "major": the comment points to a highly relevant aspect and a thorough answer is expected from the author

b "minor": the comment does not necessarily have to be answered in a detailed manner

c"linguistic": grammar, wording, spelling that affect comprehensibility of the document



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			<p>All systems have CE mark and FDA approval. Each system composed of a surgeon console and a patient side-cart with boom-mounted robotic arm(s). The surgeon operates at a console (typically in the same room as the patient) while viewing a high definition 3D image from inside the patient's body to see anatomical structures in natural colours. The patient side cart(s) is a surgical robotic assistant, with multiple arms and detachable instruments, mounted on a cart that can be positioned at the surgical site. The system translates the surgeon's hand, wrist and finger movements into real-time movements of the wristed surgical instruments. The replaceable wristed instruments (EndoWrist@384) are attached to the arms of the robot. The attached instruments have seven degrees of motion and every single instrument available is designed for a specific task (e.g. clamping, cutting, coagulating, dissecting, suturing). Another part of the surgical system is the Vision Cart: positioned tableside, the system's central processing unit component includes accessory equipment, a surgical video system, and a viewing monitor for the operating team. It is equipped with a high-definition, 3D endoscope (flexible tube with a camera and light) and image processing equipment that provides images of the patient's anatomy. This 3D HD endoscope is inserted through one of the small incisions and is held in place by one of the robotic arms^{7 9 10}.</p>		
Intuitive	37	Table 4	We would make some revisions to Table 4 regarding the CE marking and	1	Thank you. We revised the

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<p>Surgical</p>			<p>market authorization of Intuitive da Vinci Surgical Systems:</p> <p>(Note: Intuitive da Vinci Surgical Systems can be categorized by generation of products. Intuitive has now launched a fourth generation of products as described below)</p> <p>First generation:</p> <ul style="list-style-type: none"> • da Vinci® <ul style="list-style-type: none"> ○ FDA approved 2003 ○ CE Mark 2003 <ul style="list-style-type: none"> ▪ Note: CE marks do not expire per se, but, da Vinci (IS1200) is no longer on the Notified Product List and Declaration of Conformity, so it is no longer supported by our Notified Body as a CE-marked product. <p>Second generation:</p> <ul style="list-style-type: none"> • da Vinci® S <ul style="list-style-type: none"> ○ FDA approved 2005 ○ CE Mark 2007 <ul style="list-style-type: none"> ▪ Note: CE marks do not expire per se, but, da Vinci S (IS2000) is no longer on the Notified Product List and Declaration of Conformity, so it is no longer supported by our Notified Body as a CE-marked product. 		<p>description as suggested.</p>

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			Third generation: <ul style="list-style-type: none"> • da Vinci® Si <ul style="list-style-type: none"> ○ FDA approved 2009 ○ CE Mark 2009 • da Vinci® Si-e <ul style="list-style-type: none"> ○ FDA approved 2010- There is no FDA letter for this model. This is under the Si system part. ○ CE Mark 2010 Fourth generation: <ul style="list-style-type: none"> • da Vinci® Xi <ul style="list-style-type: none"> ○ FDA approved 2014 ○ CE Mark 2014 • da Vinci® X <ul style="list-style-type: none"> ○ FDA approved 2017 ○ CE Mark 2017 • da Vinci® SP <ul style="list-style-type: none"> ○ FDA approved 2018 ○ NO CE Mark 		
Health problem and current use					
-					
Clinical effectiveness					
Intuitive Surgical	56	1109	We would recommend the inclusion of the following randomized clinical trial related to rectal resection:	2	Thank you for pointing out this study. We have considered it in the assessment.

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			Wang, Gang, et al. "Male urinary and sexual function after robotic pelvic autonomic nerve-preserving surgery for rectal cancer." <i>The International Journal of Medical Robotics and Computer Assisted Surgery</i> 13.1 (2017): e1725. <i>The study strengthens EUnetHTA's conclusion that robotic-assisted surgery may 1) improve sexual function and 2) decrease postoperative complications</i>		
Safety					
DR NICOTRA	72	1469	THORACOSCOPIC INSTEAD LAPAROSCOPIC	3	Corrected
AZIENDA	72	1486	THORACOSCOPIC/OPEN INSTEAD LAPAROSCOPIC/OPEN	3	Corrected
OSPEDALIERA					
PADOVA					
Appendix					
-					

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