Appendix Table F2. Review of grey literature

Title references	Type of review	Title	ID	Manufacturer	Trade name	Common name	Classification number
510(k) Summary for Pelvex hometrainer U.S. Food and Drug Administration, 2001[1]	FDA 510 (K) review	510(k) Summary for pelvex hometrainer	K002043	Purdue Technology Park, West Lafayette, IN	pelvex	Perineometer	884.1425
510(k) summary for Vitala(tm) continence Control Device U.S. Food and Drug Administration, 2008[2]	FDA 510 (K) review	510(k) summary for Vitala(tm) continence Control Device	K083785	ConvaTec Inc. Skillman, Nj	Vitala Continence Control Device	Not reported	EZQ -C.F.R. Section 876.5900
510(k) Summary for uresta pessary U.S. Food and Drug Administration, 2008[3]	FDA 510 (K) review	510(k) Summary for uresta pessary	K081385	EastMed Inc., Halifax, Nova Scotia	Uresta Pessary	Vaginal Pessary	21CFR 884.3575
510(k) Summary for PelvicFlexer U.S. Food and Drug Administration, 2001[4]	FDA 510 (K) review	510(k) Summary for PelvicFlexer	K011688	PelvicFlex Inc., Sarasota, FL	PelvicFlexer Exercise Device	Pelvic Muscle Exerciser	884.1425
510(k) Summary for Hollister Contimed Pressure Biofeedback device U.S. Food and Drug Administration, 1996[5]	FDA 510 (K) review	510(k) Summary for Hollister Contimed Pressure Biofeedback device	K960311	Hollister Incorporated, Libertyville, IL	Hollister Contimed Pressure Biofeedback device	Not reported	Not reported
510(k) Summary of pathway vaginal emg/stimulation perineometer sensor U.S. Food and Drug Administration, 2000[6]	FDA 510 (K) review	510(k) Summary of pathway vaginal emg/stimulation perineometer sensor	K993976	The Prometheus Group, Dover, NH	Pathway Vaginal EMG/Stimulation Perineometer; Pathway Anal EMG/Stimulation Perineometer	Perineometer Sensor	876.5320; 884.1425

Appendix Table F2. Review of grey literature (continued)

Title references	Type of review	Title	ID	Manufacturer	Trade name	Common name	Classification number
501(k) summary for UroMed Alternative Bladder Control Continence Device U.S. Food and Drug Administration, 1997[7]	FDA 510 (K) review	501(k) summary for UroMed Alternative Bladder Control Continence Device	K971992	UroMed Corporation, Needham, MA	UroMed Alternative Bladder Control Continence Device	Penile Clamp/Urological Clamp	21 CFR 876.5160
510(k) Summary for InCare Pelvic Floor Therapy System with Desktop Computer U.S. Food and Drug Administration, 1997[8]	FDA 510 (K) review	510(k) Summary for InCare Pelvic Floor Therapy System with Desktop Computer	K974048	Hollister Incorporated, Libertyville, IL	InCare Pelvic Floor Therapy System with Desktop Computer	Not reported	876.5320; 884.1425
510(k) summary review for perineometer and vaginal probe U.S. Food and Drug Administration, 1997[9]	FDA 510 (K) review	510(k) summary review for perineometer and vaginal probe	K970145	BioSearch Medical Products, Inc., Somerville, NJ	Perineometer and Vaginal Probe	Not reported	884.1425
510(k) summary for vaginal stimulation/emg probe - tampon U.S. Food and Drug Administration, 1997[10]	FDA 510 (K) review	510(k) summary for vaginal stimulation/ emg probe - tampon	K971541	Hollister Incorporated, Libertyville, IL	Vaginal Stimulation/EMG Probe -Tampon		876.5320; 884.1425
510(k) Summary for innoSense pelvic floor stimulation and electromyography system U.S. Food and Drug Administration, 1997[11]	FDA 510 (K) review	510(k) Summary for innoSense pelvic floor stimulation and electromyography system	K971527	Empi Inc., St.Paul, Minnesota	Innosense Pelvic Floor Stimulation and Electromyography System	Pelvic Floor Stimulation and BioFeedback Device	876.5320; 884.1425

Appendix Table F2. Review of grey literature (continued)

Title references	Type of review	Title	ID	Manufacturer	Trade name	Common name	Classification number
510(k) summary for vaginal stimulation/emg probe - small U.S. Food and Drug Administration, 1997[12]	FDA 510 (K) review	510(k) summary for vaginal stimulation/ emg probe - small	K970602	Hollister Incorporated, Libertyville, IL	Vaginal Stimulation/EMG Probe -Small	Not reported	Not reported
510(k) summary for periform perineometric probe and pelvic floor contraction indicator U.S. Food and Drug Administration, 1998[13]	FDA 510 (K) review	510(k) summary for periform perineometric probe and pelvic floor contraction indicator	K981277	NEEN Healthcare, England, UK	Periform	Perineometer Probe	884.1425
510(k) summary review for peritron perineometer U.S. Food and Drug Administration, 1998[14]	FDA 510 (K) review	510(k) summary review for peritron perineometer	K983052	Cardio Design Pty Ltd	Peritron, Model 9300A with Anal Sensor; Model 9300V with Vaginal Sensor	Not reported	884.1425
510(k) summary for reflex treatment system U.S. Food and Drug Administration, 1999[15]	FDA 510 (K) review	510(k) summary for reflex treatment system	K994079	DesChutes Medical Products, Inc., Bend, OR	The Reflex Treatment System	Pelvic Muscle Exerciser	884.1425
510(k) Summary for Mentor EvaCare Vaginal Pessaries U.S. Food and Drug Administration, 1999[16]	FDA 510 (K) review	510(k) Summary for Mentor EvaCare Vaginal Pessaries	K993308	Mentor Corporation, Santa Barbara, CA	Mentor EvaCare Vaginal Pessaries	Vaginal Pessary	884.3575
510(k) Summary for PelvX Incontinence Dish U.S. Food and Drug Administration, 1999[17]	FDA 510 (K) review	510(k) Summary for PelvX Incontinence Dish	K990593	DesChutes Medical Products, Inc., Bend, OR	PelvX Incontinence Dish	Vaginal Pessary	884.3575
Summary for pelvic muscle therapy U.S. Food and Drug Administration, 2000[18]	FDA 510 (K) review	510(k) Summary for pelvic muscle therapy	K002830	Colonial Medical Supply, Las Vegas, Nv	Pelvic Muscle Therapy	Pelvic Muscle Exerciser	884.1425

Appendix Table F2. Review of grey literature (continued)

Title references	Type of review	Title	ID	Manufacturer	Trade name	Common name	Classification number
510(k) summary accuset sensor U.S. Food and Drug Administration, 2000[19]	FDA 510 (K) review	510(k) summary accuset sensor	K001386	PelviCare Inc., Laguna Niguel,CA	Accuset Sensor	Not reported	876.1620; 884.1425
510(k) summary for femiscan clinic system and personal system U.S. Food and Drug Administration, 2000[20]	FDA 510 (K) review	510(k) summary for femiscan clinic system and personal system	K993411	Mahoney Enterprises, East Longmeadow, MA	FemiScan Clinic System and the FemiScan Personal System	Biofeedback Monitoring device with vaginal EMG probe	876.5320; 884.1425
Summary Review for InCare Pelvic Floor Therapy System U.S. Food and Drug Administration, 2001[21]	FDA 510 (K) review	510(k) Summary Review for InCare Pelvic Floor Therapy System	K013612	Hollister Incorporated, Libertyville, IL	InCare Pelvic Floor Therapy System	Not reported	876.5320; 884.1425
510(k) Summary for InCare Pressure Biofeedback Vaginal and Anal Pressure Probes U.S. Food and Drug Administration, 2001[22]	FDA 510 (K) review	510(k) Summary for InCare Pressure Biofeedback Vaginal and Anal Pressure Probes	K013653	Hollister Incorporated, Libertyville, IL	InCare Pressure Biofeedback Vaginal Pressure Probe; InCare Pressure Biofeedback Anal Pressure Probe	Not reported	884.1425
510(k) Summary for MTI ST#1 Silicone Pessary U.S. Food and Drug Administration, 2002[23]	FDA 510 (K) review	510(k) Summary for MTI ST#1 Silicone Pessary	K020512	Medical Technology & Innovations, Inc., Lee's Summit, MO	MTI ST#1 Silicone Pessary	Vaginal Pessary	884.3575
510(k) Summary for Portex Ring Pessary U.S. Food and Drug Administration, 2002[24]	FDA 510 (K) review	510(k) Summary for Portex Ring Pessary	K012277	SIMS Registration Manager, Kent, CT	Portex Ring Pessary	Not reported	884.3575
510(k) Summary for marina Medical Silicone Pessary U.S. Food and Drug Administration, 2003[25]	FDA 510 (K) review	510(k) Summary for marina Medical Silicone Pessary	K031463	Marina Medical Instruments, Inc., Alpharetta, GA	Marina Medical silicone Pessary	Not reported	884.3575

Appendix Table F2. Review of grey literature (continued)

Title references	Type of review	Title	ID	Manufacturer	Trade name	Common name	Classification number
510(k) Summary for Kolpexin Sphere U.S. Food and Drug Administration, 2004[26]	FDA 510 (K) review	510(k) Summary for Kolpexin Sphere	K032644	ADAMED ltd., Poland	KOLPEXIN Sphere	Training Aid for Pelvic Floor Muscle or Kegel Exercise and Pessary for Vaginal Prolapse	884.3575
510(k) Summary for Intra-vaginal stress incontinence device U.S. Food and Drug Administration, 2006[27]	FDA 510 (K) review	510(k) Summary for Intra-vaginal stress incontinence device	K060526	ConTIPI Ltd., Israel, c/o ProMedic, Incorporated, Mccordsville, IN	Vaginal Pessary	Intra-vaginal stress incontinence device	884.3575
510(k) Summary for pathway vaginal/rectal perineometer probe U.S. Food and Drug Administration, [28]	FDA 510 (K) review	510(k) Summary for pathway vaginal/rectal perineometer probe	K974036	The Prometheus Group, Portsmouth, NH	Pathway Vaginal/Rectal Perineometer Probe	Perineometer Probe	884.1425
510(k) summary for anal stimulation/emg probe - w/Stop U.S. Food and Drug Administration, 1999[29]	FDA 510 (K) review	510(k) summary for anal stimulation/ emg probe - w/Stop	K990456	Hollister Incorporated, Libertyville, IL	Anal Stimulation/EMG Probe-w/Stop	Not reported	876.5320; 884.1425
510(k) Summary for uresta Pessary U.S. Food and Drug Administration, 2008[3]	FDA 510 (K) review	510(k) Summary for uresta Pessary	K083769	EastMed Inc., Halifax, Nova Scotia B3J 1S5	Uresta Pessary	Vaginal Pessary	884.3575
510(k) Summary for InCare Pelvic Floor Therapy System with Desktop Computer U.S. Food and Drug Administration, 1996[30]	FDA 510 (K) review	510(k) Summary for InCare Pelvic Floor Therapy System with Desktop Computer	K961872	Hollister Incorporated, Libertyville, IL	InCare Pelvic Floor Therapy System with Desktop Computer	Not reported	Not reported
510(k) Summary for liberty plus system pfs-300 U.S. Food and Drug Administration, 1997[31]	FDA 510 (K) review	510(k) Summary for liberty plus system pfs-300	K970077	Utah Medical Products Inc.	Liberty Plus System, PFS-300	Electrical Pelvic Floor Stimulation System with Biofeedback	876.5320; 884.1425

Appendix Table F2. Review of grey literature (continued)

Title references	Type of review	Title	ID	Manufacturer	Trade name	Common name	Classification number
Medical Review for Gelnique (oxybutynin chloride) 10% gel U.S. Food and Drug Administration, 2009[32] Staskin, 2009[33]	Medical review	Medical Review for Gelnique (oxybutynin chloride) 10% gel	22-204	Watson's laboratories	Gelnique	oxybutynin chloride	Not reported
Medical Review for PAMELOR (Brand Name Drug) U.S. Food and Drug Administration, 2001[34] No information about trials	Medical review	Medical Review for PAMELOR (Brand Name Drug)	18-012/S-024 & 18-013/S-053	Tyco Healthcare	Pamelor	Nortriptyline	Not reported
Medical Review for Sanctura (Trospium Chloride) Tablets U.S. Food and Drug Administration, 2004[35] Rudy, 2006[36] Zinner, 2004[37]	Medical review	Medical Review for Sanctura (Trospium Chloride) Tablets	21-595	Indevus Pharmaceuticals	Sanctura	Trospium chloride	Not reported
Medical Review for VesiCare (Solifenacin Succinate) Tablets U.S. Food and Drug Administration, 2004[38] Staskin, 2006[39]	Medical review	Medical Review for VesiCare (Solifenacin Succinate) Tablets	21-518	Yamanouchi Pharma America, Inc	Vesicare	Solifenacin Succinate	Not reported
Medical Review for Sanctura XR (Trospium Chloride) Extended Release Capsules U.S. Food and Drug Administration, 2007[40] Not published	Medical review	Medical Review for Sanctura XR (Trospium Chloride) Extended Release Capsules	NDA 22-103	Indevus Pharmaceuticals	Sanctura	Trospium chloride	Not reported
Medical Review for Ditropan XL(Oxybutynin Chloride) Tablets U.S. Food and Drug Administration, 1998[41] Versi, 2000[42]	Medical review	Medical Review for Ditropan XL (Oxybutynin Chloride) Tablets	NDA-20-897	Alza Corporation	DitropanXL	oxybutynin	Not reported

Appendix Table F2. Review of grey literature (continued)

Title references	Type of review	Title	ID	Manufacturer	Trade name	Common name	Classification number
Medical Review for Enablex (Clarifenacin) Extended Release Tablets U.S. Food and Drug Administration, 2004[43] Hill, 2006[44] Steers, 2005[45]	Medical review	Medical Review for Enablex (Clarifenacin) Extended Release Tablets	NDA-21-513	Novartis	Enablex	Darifenacin	Not reported
Statistical Review for Sanctura (Trospium Chloride) Tablets U.S. Food and Drug Administration, 2007[46] Staskin, 2007[47] Dmochowski, 2008[48]	Statistical review	Statistical Review for Sanctura (Trospium Chloride) Tablets	22-103	Indevus Pharmaceuticals	Sanctura XR	Trospium chloride-extended release	Not reported
Product Monograph for ENABLEX Health Canada, 2006[49] Abrams, 2008[50]	Statistical review	Product Monograph for ENABLEX	Not reported	Novartis	Enablex	Darifenacin-extended release	Not reported
Product Monograph for SANCTURA XR U.S. Food and Drug Administration, 2010[51] Staskin, 2009[52]	Statistical review	Product Monograph for SANCTURA XR	Not reported	Indevus Pharmaceuticals	Sanctura XR	Trospium chloride-extended release	Not reported
Product Monograph for VESICARE Health Canada, 2006[49] Cardozo, 2004[53] Chapple, 2004[54]	Statistical review	Product Monograph for VESICARE	Not reported	Astellas Pharma Canada, Inc.	Vesicare	Solifenacin Succinate	Not reported
NCT00168454 Posted results NCT00168454, 2008[55] Not published	Completed unpublished study from Clinicaltrials.gov	A Research Study for Patients With Overactive Bladder	191622-077	Allergan	botulinum toxin Type A	botulinum toxin	Not reported
NCT00178191 Posted results NCT00178191, [56] Not published	Completed unpublished study from Clinicaltrials.gov	Randomized Trial for Botox Urinary Incontinence	10466	University of Rochester |National Institutes of Health (NIH)	Bladder diary; Questionnaires; Urodynamics	Bladder diary; Questionnaires; Urodynamics	Not reported

Appendix Table F2. Review of grey literature (continued)

Title references	Type of review	Title	ID	Manufacturer	Trade name	Common name	Classification number
NCT00269750 A Study Comparing the Efficacy and Safety of OROS® Oxybutynin to That of Ditropan® (Immediate-release Oxybutynin) for the Treatment of Patients With Urge or Mixed Urinary Incontinence NCT00269750, 2005[57] Not published	Completed unpublished study from Clinicaltrials.gov	A Study Comparing the Efficacy and Safety of OROS® Oxybutynin to That of Ditropan® (Immediate-release Oxybutynin) for the Treatment of Patients With Urge or Mixed Urinary Incontinence	CR005968	Alza Corporation	OROS	oxybutynin chloride	Not reported
NCT00444925 Posted results NCT00444925, [58] Not published	Completed unpublished study from Clinicaltrials.gov	Clinical Trial to Evaluate the Efficacy and Safety of Fesoterodine in Comparison to Tolterodine for Overactive Bladder (OAB)	A0221008	Pfizer	Fesoterodine fumarate	Fesoterodine	Not reported
NCT00536484 Posted results NCT00536484, [59] Not published	Completed unpublished study from Clinicaltrials.gov	Fesoterodine Flexible Dose Study	A0221014	Pfizer	Fesoterodine	Fesoterodine	Not reported

Appendix Table F2. Review of grey literature (continued)

Title references	Type of review	Title	ID	Manufacturer	Trade name	Common name	Classification number
905-EC-001 Solifenacin in a flexible dose regimen with tolterodine as an active comparator in a double-blind, double-dummy, randomized overactive bladder symptom trial (STAR) U.S. Food and Drug Administration, [60] Chapple, 2005[61]	Synopsis posted in the website http://www.clinicalstudyresults.org	Solifenacin in a flexible dose regimen with tolterodine as an active comparator in a double-blind, double-dummy, randomized overactive bladder symptom trial (STAR)	905-EC-001	Astellas Pharma Europe B.V.	Solifenacin Succinate	Solifenacin	Not reported
Solifenacin in the treatment of urgency symptoms of overactive bladder in a rising dose, randomized, placebo-controlled, double-blind trial (SUNRISE) U.S. Food and Drug Administration, [62] Cardozo, 2008[63]	Synopsis posted in the website http://www.clinicalstudyresults.org	Solifenacin in the treatment of urgency symptoms of overactive bladder in a rising dose, randomized, placebo-controlled, double-blind trial (SUNRISE)	905-EC-002	Astellas Pharma Europe B.V.	Solifenacin Succinate	Solifenacin	Not reported

Appendix Table F2. Review of grey literature (continued)

Title references	Type of review	Title	ID	Manufacturer	Trade name	Common name	Classification number
Solifenacin succinate in a flexible dose regimen with simplified bladder training versus solifenacin succinate in a flexible dose regimen alone in a prospective, randomized, parallel group, overactive bladder symptom study U.S. Food and Drug Administration, [64] Mattiasson, 2009[65]	Synopsis posted in the website http://www.clinicalstudyresults.org	Solifenacin succinate in a flexible dose regimen with simplified bladder training versus solifenacin succinate in a flexible dose regimen alone in a prospective, randomized, parallel group, overactive bladder symptom study	905-EC-003	Astellas Pharma Europe B.V.	Vesicare	Solifenacin Succinate	Not reported