		FDA Indication(s) for		Proprietary	Available Clinical Evidence	
PDT Name	Description	Use	Target Population	Hardware?	and Notes	Reference(s)
						(1) empr.com/home/news
						/fda-clears-prescription
						-digital-behavioral-
						therapeutic-for-type-2
						-diabetes/
						(2)
	Prescribed in 90-day					Hmpgloballearningnetwork
	increments, the					.com
	software delivers CBT	Provide CBT to				/site/frmc/commentary
	through a mobile	patients 18 years or		No; delivered		/prescription-digital
	application in a weekly,	older with type 2		through an app		-therapeutics-ongoing
	step-by-step process to	diabetes who are	Patients <u>&gt;</u> 18 y.o. with	through an	(1) RCT (2) Health	-efforts-expand-awareness
	help patients improve	under the care of a	T2DM under care of	iPhone/iPad OR	economics analysis (3)	-integrate
AspyreRx	glycemic control	HCP.	НСР	Android	Cohort study	(3) bettertx.com/research
		Aid in the diagnosis				
	Uses an AI algorithm to	of ASD for patients				
	receive input from	18 months through 5			Several key milestones:	(1)cognoa.com/clinica
	parents or caregivers,	years of age who are	Patients ages 18 m.o.		foundational early stage	l-research/
	video analysts and	at risk of	through 72 m.o. who		development research,	(2) prnewswire.com
	health care providers	developmental delay	are at risk for	No; delivered	clinical validation, post-	/news-releases/cognoa-
	to assist physicians	based on concerns	developmental delay	through an app	FDA authorization	receives-fda-marketing
	evaluate a patient at	of a parent,	based on concerns of	through an	algorithmic optimization,	-authorization-for-first-of
	risk of Autism	caregiver, or health	a parent, caregiver, or	iPhone/iPad OR	real-world perfomance	-its-kind-autism-diagnosis
Canvas Dx	Spectrum Disorder	care provider.	healthcare provider	Android	(pragmatic analysis).	-aid-301304351.html

1		Improvement in	I		]	
		visual acuity and				
		stereo acuity in				
		amblyopia patients,				
		aged 4-<9 years,				
		associated with				
		anisometropia				
		and/or with mild				
		strabismus, having				
		received treatment				
		instructions				
		(frequency and				
		duration) as				
		prescribed by a				
		trained eyecare				
		professional.				
	Blue-red light glasses	CureSight™ is				
	that allow a child to	intended for both				
	watch any digital	previously treated				
	content with the intent	and untreated				
	to improve visual and	patients and is				
	stero acuity in patients	intended to be used				
	with amblyopia;	as an adjunct to full-				
	supported by an	time refractive				
	integrated cloud	correction, such as				
	platform that processes	glasses, which		Yes; blue-red light		(1) accessdata.fda.gov
	data from the	should also be worn		glasses (anaglyph		/cdrh_docs/pdf22
	CureSight system, eye	under the anaglyph		conversion) that	(1) Pilot prospective study	/K221375.pdf
	care provider receives a	glasses during		can must utilized	(2) One-year follow-up	(2) nova-sight.com
	comprehensive patient	CureSight™	Patients aged 4-9 y.o.	with any digital	study (3) Several posters	/publications-and-medical
CureSight	vision summary	treatment.	with amblyopia	content	published online	-posters/

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	Combines FDA-cleared					
	mobile app enabled by					
	AI technology, and					
	virtual clinical support					
	to make autonomous					
	adjustments to a					
	patient's insulin					
	prescription based on					
	their historical and					
	current glucose levels;	Calculates the next				
	patients use d-Nav	dose of insulin to aid				
	Technology before	in optimizing insulin				
	every insulin injection	management. The d-			(1) Multicenter	
	by entering their most	Nav Program is	Patients who inject		randomized controlled	
	recent sugar reading,	indicated for adults	insulin to manage		study (2) Observational	
	and then receiving a	with type 2 diabetes	their T2DM; no		studies (3) Prospective	
	personalized dose	who are injecting	specific age identified	No; iPhone/iPad,	cost analysis (4)	(1) dtxalliance.org/products
d-Nav	recommendation.	insulin.	at time of review	Android required	Prospective study	/d-nav/
		Improve attention				
	Delivered through an	function as				
	action video game;	measured by				
	designed to challenge	computer-based			Supported by a total of 5	
	pediatric patient's	testing in children			clinical studies, total of 600	
	attentional control	ages 8-12 y.o. with			pediatric patients with	
	throughout gameplay.	primarily inattentive		No; delivered	ADHD. Highlights: (1)	1
	Requires focus,	or combined-type		through an app	Multicenter, open-label	(1) endeavorrx.com
	flexibility, and ability to	ADHD, who have a		through an	effectiveness study AND	/the-research/
	manage multiple tasks	demonstrated		iPhone/iPad OR	(2) Randomized controlled	(2) dtxalliance.org/products
EndeavorRx	at one time	attention issue.	Patients ages 8-12 y.o.	Android	trial	/endeavor/

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	Medical device					
	software that					
	determines heart					
	rhythm conditions,	Self-testing by				
	with a primarily focus	patients who have				
	on the detection of Afib	been diagnosed				
	that makes use of	with, or are				
	optical sensing from a	susceptible to				
	mobile device to collect	developing, atrial				
	photoplethysmogram	fibrillation and who				
	(PPG) data; these	would like to	Patients <u>&gt;</u> 18 y.o. that	No; delivered		(1) accessdata.fda.gov
	recordings can be	monitor and record	have been diagnosed	through an app	Various studies performed:	/cdrh_docs/pdf17
	shared optionally with	their heart rhythms	with or are	through an	algorithim validation, PPG	/K173872.pdf
	a physician or	on an intermittent	susceptible to	iPhone/iPad OR	interpretation, usability for	(2) https://www.fibricheck
FibriCheck	monitoring service	basis.	developing Afib	Android	HCPs, usability for patients	.com/clinical-studies/
		Adjunctive				
		treatment of				
		symptoms				
		associated with				
		panic disorder (PD)				
		and/or				
	After completing	posttraumatic stress		Yes; patient will		
	training with a HCP or a	disorder (PTSD), to		receive Freespira		
	Freespira coach,	be used under the		device, which is		
	patients will complete	direction of a		self-contained &		(1) accessdata.fda.gov
	a 28-day home-	healthcare	Patients over 13 years	does not require	(1) Two real-world	/cdrh_docs/pdf18
	delivered protocol with	professional,	old with PTSD, panic	additional	evidence studies	/K180173.pdf
	two 17-min breathing	together with other	disorder, or suffering	equipment. Patient	(pragmatic) (2) Cost-	(2) frontiersin.org/articles
	sessions/day; there are	pharmacological	from panic attacks	will need to send	savings study with	/10.3389/fdgth.2022.
	four additional weekly	and/or non-	associated with other	device back after	Allegheny Health Network	976001/full
	virtual coaching	pharmacological	medical or behavioral	completion of	(3) Multisite benchmarking	(3) freespira.com/resources
Freespira	sessions	interventions	health conditions	therapy.	study	/

	Glooko MIDS provides directions to the patient based on a pre- planned treatment	Management of type 2 diabetes by calculating appropriate long- acting basal insulin doses for titrating insulin levels based				
	program as suggested by their HCP for	on configuration by a physician or	Patients ≥18 y.o. with			
	, titrating long acting	healthcare provider	T2DM being treated			
Glooko	insulin doses; to be	knowledgeable in	with long-acting			
Mobile Insulin	used for titrating long	the care and	insulin analogs to		Various retrospective	<ol><li>accessdata.fda.gov/</li></ol>
Dosing System	acting insulin doses	management of	manage their	No; iPhone/iPad,	studies, cost/outcomes	cdrh_docs/pdf17
(MIDS)	only	diabetes.	diabetes.	Android required	studies	/K171450.pdf
	Consists of algorithm that filters and detects irregular pulse rhythm that may be suggestive of atrial fibrillation (AF) from photoplethysmograph (PPG) data, a patient user interface to notify the patient of data collection, and a physician user interface to alert the physician when irregular pulse rhythm suggestive of	For use by patients who have been diagnosed with or are susceptible to developing atrial fibrillation and who like to monitor and record their pulse rhythms on an				
	AF is detected;	intermittent basis so	Patients >18 y.o. that	No; delivered		
	interfaces with the	that their physician	have been diagnosed	through		(4)
	LIVMOR Halo+ Home	can be alerted of	with or are	compatible	None identified at time of	(1) accessdata.fda.gov
Halo AF	Monitoring System and compatible smartwatch	detected irregular heart rhythms	susceptible to developing Afib	Samsung Smartwatch	None identified at time of review	/cdrh_docs/pdf20/ K201208.pdf
	compatible smartwatch	neart mythms		Sinditwatch	TEVIEW	K201208.pur

	to capture PPG data and sync to servers					
		Provide secure capture, storage and transmission of diabetes related healthcare information, to enhance data management, to display reports and graphs, and to aid the HCP and the patient in the				
Insulia	Software medical device that supports insulin titration for people using any brand of basal insulin	review, analysis, and evaluation of patient data in order to support effective diabetes management.	Patients ≥18 y.o. with T2DM being treated with long-acting insulin analogs to manage their diabetes.	No; iPhone/iPad, Android required	(1) Randomized controlled study with two arms	(1) dtxalliance.org/products /insulia/

standing position.   women.   muscle training   Android   (3) Single-arm trial   /leva/     Digital therapy device for amblyopia;   Improvement in visual acuity in amblyopia patients   No; designed to be   Improvement in visual acuity in amblyopia patients   No; designed to be   Improvement in visual acuity in amblyopia patients			1	1		1	l
muscles; 2) Rehabilitation and training of weak pelvic floor muscles floor strengthening to improve fecal & urinary incontinence; users are guided by the apt to perform exercisemuscles; 2) Rehabilitation and training of weak training of weakand sincentine results; Leva motion and training of weak tincontinence perform exerciseand 3) Rehabilitation and 3) Rehabilitation and or pelvic floor muscles ficantinence perform exerciseWomen with urinary incontinence, chronic fecal incontinence, chronic fecal incontinence, chronic fecal incontinence, chronic sensor is placed pelvic floor muscles perform exerciseWomen with urinary incontinence, chronic fecal incontinence, chronic fecal incontinence, chronic fecal incontinence, chronic sensor is placed intravaginally for the for the first-line session and is removed fecal incontinence (>3-monthWomen with urinary incontinence, chronic muscle weakness who want to improve or vant to improve or through an app through an ipone/iPad OR Android(1) 4RCTs (2) (1) dtalliance.org/produc (1) dtalliance.org/produc (2) monthevalImprovement in visual acuty in amblyopia;Improvement in visual acuty in amblyopia patientsNo; designed to beImprovement in visual acuty in amblyopia	i -						
Rehabilitation and training of weak pelvic floor strengthening to improve fecal & urinary incontinence; users are guided by the app to perform exercise sessions twice a day for 8-12 weeks (or until satisfied with their nad 3 Rehabilitation and training of weak pelvic floor muscles fical incontinence, users are incontinence session and is removed immediately after use. (isamontine the trained of the trainent of chronic for the first-line and/or pelvic floor muscle weakness who want to improve or session and is removed immediately after use. (isamontinence) (isamontinence) isassified with their to results); Leva motion sensor is placed intravaginally for the tecal incontinence isassified with their to results); Leva motion sensor is placed intravaginally for the tecal incontinence isassified with their tecal incontinence isassified with their tecal incontinence isassified with their tecal incontinence intravaginally for the tecal incontinence isassified with their tecal incontinence isassified with their tecal incontinence intravaginally for the tecal incontinence immediately after use. (isamonth tecal incontinence immediately after use. (isamonth tecal incontinence isasse of feces) in home pelvic floor muscle trainingNo; delivered through an app through an app through an app through an app(1) 4 RCTs (2) Retrospective cohort study (1) dtxalliance.org/produce (1) dtxalliance.org/produce (1) dtxalliance in muscle trainingAndroid(1) 4 RCTs (2) No; designed to be(1) dtxalliance.org/produce (1) dtxalliance.org/produce (2) Single-arm trial.evaDigital therapy device for amblyopia patientsImprovement in visual autity in amblyopia patients	1		-				
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Intended for pelvic floor strengthening to improve fecal & urinary incontinence; users are guided by the app to perform exercise sessions twice a day for satisfied with their results); Leva motion sensor is placed immediately after use. performed in a performed in a performed in a performed in a performed in a muscle field incontinence session and is removed immediately after use. (>3Women with urinary incontinence incontinence, chronic fecal incontinence, chronic fecal incontinence, instrawginally for the for the first-line and/or pelvic floor muscle weakness who want to improve or resolve these through an app through an app through an app through an performed in a passage of feces) in passage of feces) in home pelvic floor muscle trainingNo; delivered through an app(1) 4 RCTs (2) Retrospective cohort study (1) dtxalliance.org/produc /leva/.evaDigital therapy device for amblyopia;Improvement in amblyopia patientsNo; designed to beNo; designed to be	1						
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sensor is placed intravaginally for the duration of the exercise session and is removed immediately after use.pelvic floor muscles for the first-line treatment of chronic fecal incontinence want to improve or symptoms with at- performed in a standing position.pelvic floor floor incontinence want to improve or symptoms with at- muscle trainingNo; delivered through an app through an app iPhone/iPad OR Android(1) 4 RCTs (2) Retrospective cohort study (1) dtxalliance.org/product (1) dtxalliance.org/product (1) dtxalliance.org/product (1) dtxalliance.org/product (1) dtxalliance.org/product (1) dtxalliance.org/productnewaImprovement in visual acuity in amblyopia;Improvement in amblyopia patientsNo; designed to beImprovement in No; designed to be	I	satisfied with their		Women with urinary			
intravaginally for the duration of the exercise session and is removed immediately after use. Exercise sessions are performed in a standing position.for the first-line treatment of chronic fecal incontinence (>3-month uncontrolled muscle weakness who symptoms with at- home pelvic floor muscle trainingNo; delivered through an app through an app th	1	results); Leva motion	and training of weak	incontinence, chronic			
duration of the exercise session and is removed immediately after use. Exercise sessions are performed in a standing position.treatment of chronic fecal incontinence (>3-month uncontrolled passage of feces) in muscle trainingNo; delivered through an app iPhone/iPad OR AndroidNo; delivered through an app (1) 4 RCTs (2) Retrospective cohort study (3) Single-arm trial(1) dtxalliance.org/product (1) dtxalliance.org/product (1) dtxalliance.org/product (1) dtxalliance.org/product.evaDigital therapy device for amblyopia;Improvement in visual acuity in amblyopia patientsNo; designed to beNo; designed to be	I	sensor is placed	pelvic floor muscles	fecal incontinence,			
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performed in a standing position.   passage of feces) in women.   home pelvic floor muscle training   iPhone/iPad OR Android   Retrospective cohort study (1) dtxalliance.org/productive //eva////eva///eva////eva   eva///eva	I	immediately after use.	(>3-month	resolve these	through an app		
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Digital therapy device Improvement in visual acuity in amblyopia; No; designed to be	1	performed in a	passage of feces) in	home pelvic floor	iPhone/iPad OR	Retrospective cohort study	(1) dtxalliance.org/products
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for amblyopia; amblyopia patients No; designed to be	1	ļ į					
	1		-				
	1	for amblyopia;	amblyopia patients				
	I	incorporates dichoptic	4-7 y.o., associated		used with		
presentations on visual with anisometropia commercially	I	•			· · · · · · · · · · · · · · · · · · ·		
displays through and/or with mild available Head-	I		-				
therapeutic algorithms strabismus as Patients 4-7 y.o. with Mounted Displays (1) RCT (2) Open-label pilot (1) accessdata.fda.gov/	1			-			
to treat amblyopia or prescribed by a amblyopia, associated that are study (3) Single-center, cdrh_docs/reviews	1						<u> </u>
to improve visual acuity trained eye-care with anisometropia compatible with open-label design (4) /DEN210005.pdf	1		-	-			•
	Luminopia		•			- ,	
One     amblyopia     Intended for both     strabismus     application     patient involvement     /clinical-data	One	amblyopia	Intended for both	strabismus	application	patient involvement	/clinical-data

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		previously treated	1	(	1	
		and untreated	1		1	1
		patients; however,	1		1	1 1
		patients with >12	1		1	ı 📕
		months of prior	1		1	ı 📕
		treatment (other	1		1	ı 📕
		than refractive	1		1	ı 📕
		correction) have not	1		1	1
		been studied	1		1	1
	+	,,	1 4		1 1	(1) assets.website-files.com
		1	1		1	/61f48988f687c00c6032
		1	1		1	c430/61f48988f687c071
	Three-month, patient	1	1		1	e032c514_03-0007-002%2
	tailored interactive	1	1		1	0Rev%20B_Parallel%20
	program designed to	1	1	No; delivered	1	Mobile%20US_Labeling
Mahana IBS	reduce severity of IBS	1	1	through an app	1	_Clinician%20Information%
(Previously	symptoms through	Indicated as 3-	1	through an	1	_Clinician%20information% 20Sheet.pdf
known as		month treatment for	Adulta > 22 y a with	iPhone/iPad OR	(1) Multicenter	(2) https://gut.bmj.com
	cognitive behavioral		Adults <u>&gt;</u> 22 y.o. with	· · · · · · · · · · · · · · · · · · ·	. ,	
Parallel)	therapy	patients with IBS	IBS	Android	randomized clinical trial	/content/68/9/1613.long
	Focuses on maximizing	1	1		1	1
	the recovery potential	1	1		1	1
	of patients after a	1	1		1	1
	stroke or brain injury.	1 !	1		1	1
	Software includes	Medical device	1		1	i l
	rehabilitation exercises	software used in	1		1	1
	for the upper	combination with	1		1	1
	extremity, trunk, and	the Microsoft Kinect	1		1	1
	lower extremity; audio-	v2 and Leap Motion	1		1	1
	visual feedback and	controller that	1		1	1
	graphic movement	supports the	Patients that have	No; software	1	(1) accessdata.fda.gov/
1	Biapine moteriene			( ) II ( ) I ( ) ( ) ( ) ( ) ( ) ( ) ( )	1	cdrh_docs/pdf17
	representations for	physical	experienced a stroke	delivered through	1	cum_uocs/purt/
		physical rehabilitation of	experienced a stroke or brain injury; no	delivered through Microsoft Kinect		/K173931.pdf
MindMotion	representations for				None identified at time of	
MindMotion GO	representations for patients; and patient	rehabilitation of	or brain injury; no	Microsoft Kinect	None identified at time of review	/K173931.pdf

	professional. Patient assessment, exercise guidance, and approval by the medical professional is required prior to use.					
	Vision function test					
	provided as a downloadable app on					
	to the user's supplied					
	cell phone or tablet					
	which implements a					
	shape discrimination	Detection and				
	hyperacuity vision test	characterization of				
	which allows patients	central 3 degrees				
	to perform their own	metamorphopsia				
	vision test at home; if a	(visual distortion) in				
	significant worsening of vision function is					
	detected the physician	maculopathy, including age-related				
	will be notified and	macular				
	provided access to the	degeneration and	Patients with age-			
	vision self-test results	diabetic retinopathy,	related macular			
	so that they can decide	and as an aid in	degeneration, diabetic			(1) accessdata.fda.gov
	whether the patient	monitoring	retihnopathy, and	No; delivered		/cdrh_docs/pdf14
	needs to be seen	progression of	other retinal	through an app		/K143211.pdf
	sooner than their next	disease factors	conditions; no specific	through an		(2) classic.clinicaltrials.gov
	already scheduled	causing	age identified at time	iPhone/iPad OR	(1) Observational, case-	/ct2/show/record
myVisionTrack	appointment	metamorphopsia.	of review	Android	only study	/NCT01728883

1		1			-	, <b>/</b>
		Non-	1		· · · · · · · · · · · · · · · · · · ·	
		pharmacological,	1		· · · · · · · · · · · · · · · · · · ·	1
		non- invasive,	1		· · · · · · · · · · · · · · · · · · ·	I 📕
		wireless, wearable,	'		· · · · · · · · · · · · · · · · · · ·	1
		battery-operated,	'		· · · · · · · · · · · · · · · · · · ·	1
		remote electrical	'		· · · · · · · · · · · · · · · · · · ·	1
		neuromodulation	'		· · · · · · · · · · · · · · · · · · ·	1
		(REN) stimulation	'		· · · · · · · · · · · · · · · · · · ·	1
		device for the	'		· · · · · · · · · · · · · · · · · · ·	1
		treatment of	'		· · · · · · · · · · · · · · · · · · ·	1
		migraine. Nerivio is	'		· · · · · · · · · · · · · · · · · · ·	1 7
		self-administered by	For migraine patients		· · · · · · · · · · · · · · · · · · ·	1 7
	Wireless wearable	the patient,	with or without aura,		· · · · · · · · · · · · · · · · · · ·	1 7
	battery-operated	controlled by a	≥12 y.o. For those		(1) Pragmatic trial (2)	1
	stimulation unit	smartphone app,	seeking a clinically-		Prospective, multi-center,	1
	controlled by a	and FDA cleared for	proven drug-free		open-label trial (3)	
	smartphone software	acute treatment of	solution, or those that	No; delivered	Retrospective, survey	
	application; treatments	migraine with or	do not respond to	through an app	study (4) Several (>5)	
	are self-administered	without aura in	prescribed	through an	prospective, open-label	
	by the user at the onset		medications and/or	iPhone/iPad OR	studies (5) Several sham-	(1) dtxalliance.org/products
Nerivio	of a migraine attack.	age or older.	cannot tolerate AEs	Android	controlled studies	/nerivio/
		Provide vibrotactile			· · · · · · · · · · · · · · · · · · ·	1
		feedback on an	'		· · · · · · · · · · · · · · · · · · ·	1
	Digital therapeutic	Apple Watch based			· · · · · · · · · · · · · · · · · · ·	1
	system that	on an analysis of			· · · · · · · · · · · · · · · · · · ·	1
	temporarily reduces	heart rate and	'		· · · · · · · · · · · · · · · · · · ·	
	sleep disturbance	motion during sleep	'		· · · · · · · · · · · · · · · · · · ·	
	related to nightmares	for the temporary	Adults <u>&gt;</u> 22 y.o who	No; software	· · · · · · · · · · · · · · · · · · ·	
	through vibrotactile	reduction of sleep	suffer from nightmare	delivered through	· · · · · · · · · · · · · · · · · · ·	
	feedback during sleep	disturbance related	disorder or have	AppleWatch and	(1) Randomized sham-	(1) nightware.com/
NightWare	cycle	to nightmares	nightmares from PTSD	iPhone	controlled clinical trial	scientific-literature/

	Three-month					
	treatment for patients with abdominal pain					
	due to IBS that is					
	designed to induced					
	deep physical					
	autonomic relaxation					
	followed by	Provide behavioral			No studies specific to	
	metphorical	therapy through gut-			device; rather, efficacy and	
	storytelling with a	directed		No; delivered	safety built on previous	(1) accessdata.fda.gov
	combination of	hypnotherapy for		through an app	research that describes	/cdrh docs/pdf21
	direct/indirect	adults >22 y.o. and		through an	efficacy of hypontherapy	/K211463.pdf
	suggestions at somatic	older who have been	Adults >22 y.o. with	iPhone/iPad OR	and behavioral therapy for	(2) regulorahcp.com/
Regulora	control mechanisms	diagnosed with IBS	IBS	Android	IBS	resources/
		Provide adjunctive				
		treatment based on				
		cognitive behavioral				
		therapy skills and				
	Virtual reality device	other evidence-				
	intended to provide	based behavioral				
	behavioral therapy for	methods for patients		Yes; RelieVRx kit		
	patients with pain;	(age 18 and older)		includes the		
	treatment is self-	with a diagnosis of	Adults <u>&gt;</u> 18 y.o. with a	optimized device		
	administered over 8	chronic lower back-	diagnosis of chronic	for VRx,	(1) Randomized,	
RelieVRx	weeks in the comfort of	pain (defined as	lower back-pain	headset/controller,	controlled, double-blind	
(Previously	a patient's home with	moderate to severe	(moderate to severe	screen, face pan,	trial *FYI Class 2 Active	(1) appliedvr.io/product
known as	an average daily	pain lasting longer	pain lasting longer	amplifier, and	recall as of 06/2023 due to	(2) relievrx.com/
EaseVRx)	session of 7 mins	than three months)	than three months)	platform	device malfunctioning	clinical-results#trial-design

I		Í	1		1	1
	Delivers behavioral		1			
	therapy modeled on		1			
	the Community		1			
	Reinforcement		1			
	Approach (CRA), which		1			
	is a specific form of CBT	!	1			
	designed for patients	Provide cognitive				
	with SUD; combines	behavioral therapy,	Patients with SUD and			
	CRA and fluency	as an adjunct to a	concurrently under			
	training in conjunction	contingency	treatment for			
	with Contingency	management	addiction to			
	Management to	system, for patients	stimulants, alcohol			
	support and incentivize	18 years of age and	plus another			
	patients with SUD in	older, enrolled in	substance, marijuana,	No; delivered		
	achieving abstinence	outpatient	cocaine, opioids	through an app	(1) Randomized controlled	
	and retention in	treatment under the	(when not the primary	through an	design (2) Multisite	
	outpatient SUD	supervision of a	substance of abuse),	iPhone/iPad OR	randomized controlled	(1) dtxalliance.org/products
reSET	treatment.	clinician.	and other substances	Android	design	/reset/
		Intended to increase	1			
		retention of patients	1			
		with OUD in	1			
		outpatient	1			
		treatment by	Patients with OUD, as			
	12-week (84-day)	providing CBT, as an	an adjunct to			
	software application to	adjunct to	outpatient treatment			
	be used as an adjunct	outpatient	that includes			
	to outpatient	treatment that	transmucosal			
	treatment using	includes	buprenorphine and			
	transmucosal	transmucosal	contingency			
	buprenorphine and	buprenorphine and	management, for	No; delivered		
	contingency	contingency	patients <a>18</a> y.o. who	through an app		
		manage and and far	are currently under	through an	(1) Block-randomized,	1
	management to	management, for	-			
reSET-O	management to increase retention of patients with OUD	patients 18 years or older who are	the supervision of a clinician	iPhone/iPad OR Android	unblinded, parallel, 12- week treatment trial	(1) dtxalliance.org/products /reset-o/

		currently under the supervision of a clinician.				
	9-week device for chronic insomnia; delivers CBT-I which focuses on addressing the maladaptive behaviors, routines, and dysfunctional thoughts that perpetuate sleep problems, regardless of	Provide a neurobehavioral intervention (CBT for Insomnia — CBT-I) to patients 22 years of age and older with chronic insomnia. Intended to improve		No; delivered through an app through an		(1) accessdata.fda.gov /cdrh_docs/pdf19/ K191716.pdf
Somryst	the original source of the sleep problem	a patient's insomnia symptoms.	Patients <a>22 y.o. with chronic insomnia</a>	iPhone/iPad OR Android	(1) Randomized controlled trial	<ul><li>(2) dtxalliance.org/products</li><li>/somryst/</li></ul>