

## 新北市政府衛生局 函

地址：220205新北市板橋區英士路192之1號3樓

承辦人：王佩心

電話：(02)22577155 分機2352

傳真：(02)22536548

電子信箱：AN8351@ntpc.gov.tw



24158

新北市三重區重新路5段646號8樓

受文者：社團法人新北市藥師公會

發文日期：中華民國113年10月17日

發文字號：新北衛食字第11320110331號

速別：普通件

密等及解密條件或保密期限：

附件：產品型號及特定批號資料1份

主旨：有關台灣曲克股份有限公司之「"曲克"阿迫企微導管(衛署醫器輸字第020461號)」及「"曲克"親水性塗層微細導管(衛署醫器輸字第020466號)」特定批號醫療器材自願性回收一案，回收產品批號詳如附件，請惠予轉知所屬會員，如有案內批號產品請勿再使用或販售，並儘速配合回收事宜，請查照。

說明：

- 一、依據台灣曲克股份有限公司113年10月8日曲克品字第2024100801號函辦理。
- 二、案係旨揭公司查旨揭特定批號醫療器材標籤顯示錯誤有效日期，可能發生潛在不良事件風險，故啟動回收，回收產品資訊詳如「產品型號及特定批號資料」。
- 三、為保障民眾使用藥物安全，請惠予轉知所屬會員，如有案內批號產品請勿再使用或販售，並儘速配合回收事宜。
- 四、副本抄送各縣市衛生局，請惠予協助轉知轄內機構，如有案內批號產品請勿再使用，並儘速配合回收事宜。

正本：社團法人新北市醫師公會、社團法人新北市藥師公會、新北市藥劑生公會、新北市醫療器材商業同業公會、新北市西藥商業同業公會

副本：各縣市政府衛生局(含附件)

局長 陳潤秋



本案依分層負責規定授權業務主管決行





COOK MEDICAL LLC  
 400 DANIELS WAY PO BOX 4195  
 BLOOMINGTON, IN 47402-4195  
 PHONE: 812.339.2235 TOLL FREE: 800-457-4500 FAX: 800.554.8335  
 WWW.COOKMEDICAL.COM

O

Table 1 – Product Information, Approach® CTO Micro Wire Guide

REFERENCE PART NUMBER (RPN)	ORDER NUMBER (GPN)	DEVICE IDENTIFIER (DI)	LOT NUMBER	LABEL EXPIRATION DATE	CORRECT EXPIRATION DATE
CMW-14-190-12G	G50787	(01)0082700 2507876(17)	15763571	11/17/2028	2/4/2026
			15783003	12/3/2028	3/28/2026
			NS15849650	1/15/2029	5/9/2026
			NS15821244	12/27/2028	5/9/2026
			15773059	11/27/2028	1/25/2028
CMW-14-190-18G	G50788	(01)0082700 2507883(17)	15898546	2/14/2029	8/5/2026
			NS15849651	1/15/2029	8/5/2026
			15811662	12/18/2028	8/5/2026
			15763579	11/17/2028	8/5/2026
			15943888	3/12/2029	1/15/2027
			15925115	12/2/2029	1/15/2027
			15802931X	12/12/2028	1/15/2028
			15802931	12/12/2028	1/15/2028
			15769462	11/22/2028	1/15/2028
			CMW-14-190-25G	G50789	(01)0082700 2507890(17)
15849652	1/15/2029	7/9/2025			
15802932	12/12/2028	7/9/2025			
15791923	12/6/2028	7/9/2025			
15891915	2/9/2029	8/6/2025			
CMW-14-190-6G	G50786	(01)0082700 2507869(17)	15891914	2/9/2029	8/6/2025
			15800162	12/12/2028	7/8/2027
CMW-14-300-12G	G50791	(01)0082700 2507913(17)	15794897	12/7/2028	4/23/2026
			15718982	10/20/2028	4/23/2026
			15763605	11/17/2028	4/23/2026
			15885578	2/6/2029	7/17/2026
			15858395	1/22/2029	7/17/2026
			NS15843567	1/11/2029	7/17/2026
			15802924	12/12/2028	7/17/2026
			15763577	11/17/2028	7/17/2026
			15763552	11/17/2028	7/17/2026
			15763604	11/17/2028	7/17/2026
			15763561	11/17/2028	7/17/2026
			15943896	3/12/2029	8/18/2026
			15915909	2/24/2029	8/18/2026
			15898543	2/14/2029	8/18/2026
			15891916	2/9/2029	8/18/2026
15858399	1/22/2029	8/18/2026			



COOK MEDICAL LLC  
 400 DANIELS WAY PO BOX 4195  
 BLOOMINGTON, IN 47402-4195  
 PHONE: 812.339.2235 TOLL FREE 800-457-4500 FAX 800-554-0335  
 WWW.COOKMEDICAL.COM

Table 1 – Product Information (Continued), Approach® CTO Micro Wire Guide

REFERENCE PART NUMBER (RPN)	ORDER NUMBER (GPN)	DEVICE IDENTIFIER (DI)	LOT NUMBER	LABEL EXPIRATION DATE	CORRECT EXPIRATION DATE
CMW-14-300-6G	G50790	(01)0082700 2507906(17)	15778251	11/29/2028	2/27/2026
			15763597	11/17/2028	2/27/2026
			15907474	2/20/2029	3/28/2026
			15891908	2/9/2029	3/28/2026
			NS15849653	1/15/2029	3/28/2026
			NS15829388	1/3/2029	3/28/2026
			NS15800160	12/12/2028	3/28/2026
			15794898	12/7/2028	3/28/2026
			NS16008457	4/15/2029	4/23/2026
CMW-14-300-18G	G50792	(01)0082700 2507920(17)	15718980	10/20/2028	11/7/2026
			15794895	12/7/2028	11/26/2026
			NS15773060	11/27/2028	11/26/2026
			15763585	11/17/2028	11/26/2026
			15763563	11/17/2028	11/26/2026
			15763553	11/17/2028	12/19/2026
			15835853	1/8/2029	1/20/2027
			NS15811659	12/18/2028	1/20/2027
			15802926	12/12/2028	1/20/2027
			15765959	11/20/2028	1/20/2027
			15900750	2/15/2029	1/29/2027
			NS15898545	2/14/2029	1/29/2027
			15891910	2/9/2029	1/29/2027
			NS15898544	2/14/2029	1/29/2027
			15858397	1/22/2029	1/29/2027
			15863270	1/23/2029	1/29/2027
			15802933	12/12/2028	1/29/2027
			15913326	2/22/2029	2/17/2027
			15891906	2/9/2029	2/17/2027
			15892397	2/10/2029	2/17/2027
15915903	2/24/2029	2/26/2027			
15945781	3/13/2029	3/18/2027			
15971786	3/22/2029	3/24/2027			



COOK MEDICAL LLC  
 400 DANIELS WAY PO BOX 4195  
 BLOOMINGTON, IN 47402-4195  
 PHONE: 812.339.2235 TOLL FREE: 800-457-4500 FAX: 800.554.8335  
 WWW.COOKMEDICAL.COM

Table 1 – Product Information (Continued), Approach® CTO Micro Wire Guide

REFERENCE PART NUMBER (RPN)	ORDER NUMBER (GPN)	DEVICE IDENTIFIER (DI)	LOT NUMBER	LABEL EXPIRATION DATE	CORRECT EXPIRATION DATE
CMW-14-300-25G	G50793	(01)0082700 2507937(17)	15718981	10/20/2028	4/23/2026
			15794896	12/7/2028	6/19/2026
			15763609	11/17/2028	6/19/2026
			15765960	11/20/2028	6/19/2026
			15763591	11/17/2028	6/19/2026
			15731211	10/28/2028	6/19/2026
			15763580	11/17/2028	6/19/2026
			15885579	2/6/2029	7/10/2026
			15835856	4/20/2028	7/10/2026
			15811660	12/18/2028	7/10/2026
			15943897	3/12/2029	7/18/2026
			NS15945783	3/13/2029	7/18/2026
			15863271	1/23/2029	7/18/2026
			15800156	12/12/2028	7/18/2026
			15915902	2/24/2029	8/19/2026
			15891911	2/9/2029	8/19/2026
			NS15821243	12/27/2028	8/19/2026
NS15974440	3/25/2029	8/28/2026			
15892398	2/10/2029	8/28/2026			
NS16006214	4/12/2029	9/5/2026			

Cre  
 Philip  
 1-2026



COOK MEDICAL LLC  
 400 DANIELS WAY PO BOX 4195  
 BLOOMINGTON, IN 47402-4195  
 PHONE: 812.339.2235 TOLL FREE: 800.457.4500 FAX: 800.554.8335  
 WWW.COOKMEDICAL.COM

Table 2 – Product Information, Approach® Hydro ST Micro Wire Guide

REFERENCE PART NUMBER (RPN)	ORDER NUMBER (GPN)	DEVICE IDENTIFIER (DI)	LOT NUMBER	LABEL EXPIRATION DATE	CORRECT EXPIRATION DATE
HMW-14-135-ST	G52937	(01)0082700 2529373(17)	15735501	10/31/2026	9/14/2024
			15765954	11/20/2026	9/14/2024
			15907468	2/20/2027	10/8/2024
			15863269	1/23/2027	10/8/2024
			15874634	1/30/2027	10/8/2024
			15974437	3/25/2027	2/6/2025
			15943872	3/12/2027	2/6/2025
			15943886	3/12/2027	2/6/2025
HMW-14-190-ST	G52938	(01)0082700 2529380(17)	15829376	1/3/2027	11/19/2024
			15835857	1/8/2027	11/19/2024
			15831156	1/4/2027	11/19/2024
			NS15835858	1/8/2027	11/19/2024
			15811657	12/18/2026	11/19/2024
			15811656	12/18/2026	11/19/2024
			15821245	12/27/2026	11/19/2024
			NS15821246	12/27/2026	11/19/2024
			15800166	12/12/2026	11/19/2024
			NS15802918	12/12/2026	11/19/2024
			15800165	12/12/2026	11/19/2024
			NS15794893	12/7/2026	11/19/2024
			NS15765956	11/20/2026	11/19/2024
			NS15783001	12/3/2026	11/19/2024
			15778260	11/29/2026	11/19/2024
			15726043	10/25/2026	11/19/2024
			15765955	11/20/2026	11/19/2024
			15726044	10/25/2026	11/19/2024
			15765947	11/20/2026	11/19/2024
			NS15769470	11/22/2026	11/19/2024
			15908739	2/20/2027	11/30/2024
			NS15915900	2/24/2027	11/30/2024
			15874633X	1/30/2027	11/30/2024
			15894221	2/12/2027	11/30/2024
			15891903	2/9/2027	11/30/2024
			15885580	2/6/2027	11/30/2024
			15894222	2/12/2027	11/30/2024
			15874633	1/30/2027	11/30/2024
			15858389	1/22/2027	11/30/2024
			15849644	1/15/2027	11/30/2024
			15952502	3/18/2027	1/1/2025
			15988603	4/3/2027	2/6/2025
15979320	3/27/2027	2/6/2025			



COOK MEDICAL LLC  
 400 DANIELS WAY PO BOX 4195  
 BLOOMINGTON, IN 47402-1195  
 PHONE: 812.339.2235 TOLL FREE: 800-457-4500 FAX: 800.554.8335  
 WWW.COOKMEDICAL.COM

Table 2 – Product Information (Continued), Approach® Hydro ST Micro Wire Guide

REFERENCE PART NUMBER (RPN)	ORDER NUMBER (GPN)	DEVICE IDENTIFIER (DI)	LOT NUMBER	LABEL EXPIRATION DATE	CORRECT EXPIRATION DATE
HMW-14-300-ST	G52939	(01)0082700 2529397(17)	15726042X	10/25/2026	10/8/2024
			NS15720964	10/23/2026	10/8/2024
			15718979	10/20/2026	10/8/2024
			15731209	10/28/2026	10/8/2024
			15731210	10/28/2026	10/8/2024
			15726042	10/25/2026	10/8/2024
			15718978	10/20/2026	10/8/2024
			15765951	11/20/2026	10/8/2024
			15765953	11/20/2026	10/8/2024
			15726045	10/25/2026	10/9/2024
			15720963	10/23/2026	10/9/2024
			15765949	11/20/2026	10/9/2024
			15735502	10/31/2026	10/9/2024
			15765948	11/20/2026	10/9/2024
			15765952	11/20/2026	10/9/2024
			NS15802922	12/12/2026	10/16/2024
			15802919	12/12/2026	10/16/2024
			NS15794892	12/7/2026	10/16/2024
			NS15800168	12/12/2026	10/16/2024
			15794891	12/7/2026	10/16/2024
			15778257	11/29/2026	10/16/2024
			15765950	11/20/2026	10/16/2024
			15769465	11/22/2026	10/16/2024
			15769467	11/22/2026	10/16/2024
			15769463	11/22/2026	10/16/2024
			15769466	11/22/2026	10/16/2024
			15769464	11/22/2026	10/16/2024
			NS15769468	11/22/2026	10/16/2024
			NS15821249	12/27/2026	10/23/2024
			15816910	12/21/2026	10/23/2024
			15821250	12/27/2026	10/23/2024
			15794890	12/7/2026	10/23/2024
			15800167	12/12/2026	10/23/2024
			15802920	12/12/2026	10/23/2024
			15778258	11/29/2026	10/23/2024
			15778259	11/29/2026	10/23/2024
			15843560X	1/11/2027	11/19/2024
			15885581	2/6/2027	11/19/2024
			15863268	1/23/2027	11/19/2024
			15891901	2/9/2027	11/19/2024
15894227	2/12/2027	11/19/2024			
15891902	2/9/2027	11/19/2024			
15894223	2/12/2027	11/19/2024			
15879455	2/1/2027	11/19/2024			
15885583	2/6/2027	11/19/2024			
15885584	2/6/2027	11/19/2024			



COOK MEDICAL LLC  
 400 DANIELS WAY PO BOX 4195  
 BLOOMINGTON, IN 47402-4195  
 PHONE: 812.339.2235 TOLL FREE: 800-457-4500 FAX: 800.554.8335  
 WWW.COOKMEDICAL.COM

Table 2 – Product Information (Continued), Approach® Hydro ST Micro Wire Guide

REFERENCE PART NUMBER (RPN)	ORDER NUMBER (GPN)	DEVICE IDENTIFIER (DI)	LOT NUMBER	LABEL EXPIRATION DATE	CORRECT EXPIRATION DATE
HMW-14-300-ST	G52939	(01)0082700 2529397(17)	15863267	1/23/2027	11/19/2024
			15885582	2/6/2027	11/19/2024
			15863266	1/23/2027	11/19/2024
			NS15892395	2/10/2027	11/19/2024
			15858391	1/22/2027	11/19/2024
			NS15858393	1/22/2027	11/19/2024
			15858390	1/22/2027	11/19/2024
			NS15845747	1/13/2027	11/19/2024
			15829375	1/3/2027	11/19/2024
			15831159	1/4/2027	11/19/2024
			15831157	1/4/2027	11/19/2024
			15845746	1/13/2027	11/19/2024
			15845745	1/13/2027	11/19/2024
			15845744	1/13/2027	11/19/2024
			15829377	1/3/2027	11/19/2024
			15843561	1/11/2027	11/19/2024
			15811658	12/18/2026	11/19/2024
			15816909	12/21/2026	11/19/2024
			NS15821247	12/27/2026	11/19/2024
			15821248	12/27/2026	11/19/2024
			15802921	12/12/2026	11/19/2024
			15769469	11/22/2026	11/19/2024
			15902070X	2/16/2027	11/29/2024
			15902069	2/16/2027	11/29/2024
			15902070	2/16/2027	11/29/2024
			15902068	2/16/2027	11/29/2024
			15894224	2/12/2027	11/29/2024
			15894225	2/12/2027	11/29/2024
			15894226	2/12/2027	11/29/2024
			15892394	2/10/2027	11/29/2024
			15945800	3/13/2027	11/30/2024
			15943885X	3/12/2027	11/30/2024
			15943885	3/12/2027	11/30/2024
			15943884	3/12/2027	11/30/2024
			15943878	3/12/2027	11/30/2024
			15943876	3/12/2027	11/30/2024
			15943875	3/12/2027	11/30/2024
			15943879	3/12/2027	11/30/2024
			15943877	3/12/2027	11/30/2024
			15943880	3/12/2027	11/30/2024





COOK MEDICAL LLC  
 400 DANIELS WAY PO BOX 4195  
 BLOOMINGTON, IN 47402-4195  
 PHONE: 812.339.2235 TOLL FREE 800-457-4500 FAX: 800.554.8335  
 WWW.COOKMEDICAL.COM

**Table 2 – Product Information (Continued), Approach® Hydro ST Micro Wire Guide**

REFERENCE PART NUMBER (RPN)	ORDER NUMBER (GPN)	DEVICE IDENTIFIER (DI)	LOT NUMBER	LABEL EXPIRATION DATE	CORRECT EXPIRATION DATE
HMW-14-300-ST	G52939	(01)0082700 2529397(17)	15943883	3/12/2027	11/30/2024
			15995199	4/5/2027	2/6/2025
			15995198	4/5/2027	2/6/2025
			15958703	3/20/2027	2/6/2025
			15952500	3/18/2027	2/6/2025
			15971772	3/22/2027	2/6/2025
			15971780	3/22/2027	2/7/2025
			15971775	3/22/2027	2/7/2025
			15971774	3/22/2027	2/7/2025
			15988604	4/3/2027	2/7/2025
15971776	3/22/2027	2/7/2025			