FDA CDRH

General and Plastic Surgery Devices
Advisory Committee Meeting

July 28-29, 2022

*****Virtual*****

As required by section 513(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), the Food and Drug Administration (FDA) is convening the General and Plastic Surgery Devices Advisory Panel (the Panel) for the purposes of obtaining recommendations about the reclassification of skin lesion analyzers (SLAs) and to discuss appropriate controls necessary to mitigate the risks to health and assure the safety and effectiveness of these devices.

FDA is holding this panel meeting to obtain input on the risks and benefits of SLAs for external use. The Panel will be asked to recommend to FDA whether SLAs should be down classified from Class III into Class II (subject to General and Special Controls). The Panel will be asked to discuss the types of evidence (including clinical evidence) that would be helpful to support certain indications as well as appropriate special controls necessary to mitigate the risks to health and assure the safety and effectiveness of these devices

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Day 1 Agenda: SLA General Topics

9:00 a.m.	Call to Order, Opening Remarks, and Introduction of the Committee	Panel Chair
9:05 a.m.	Conflict of Interest Statement	Candace Nalls Designated Federal Officer
	Introduction	
9:15 a.m.	Introductory Remarks and Panel Overview	Colin Kejing Chen, Ph.D.
	FDA's Oversight of SLA Devices	
9:25 a.m.	Overview of Skin Lesions	Jennifer Bai, M.D.
9:40 a.m.	Skin Lesion Analyzer Device Landscape	Jianting Wang, Ph.D.
9:55 a.m.	Special Considerations: Diagnostic Accuracy and Ground Truth	Henry Lee, M.D.
10:15 a.m.	Special Considerations: Benefit/Risk and Prevalence	Scott L. Kominsky, Ph.D.
10:30 a.m.	Clarifying Questions from the Panel	Panel Chair
	External Speaker Presentations	
10:45 a.m.	Invited Presenters	Glenn Cohen J.D. Adewole Adamson, M.D., MPP
11:15 a.m.	**Open Public Hearing Session*	

Noon	Lunch	
1:00 p.m.	Panel Deliberations	Panel Chair
	FDA Questions	
2:30 p.m.	FDA Questions	Rudy Andriani, M.S.
4:00 p.m.	FDA Summation	Jianting Wang, Ph.D.
4:10 p.m.	Panel Summation	Panel Chair
4:20 p.m.	Adjourn	

Day 2 Agenda: Reclassification of SLA Devices

9:00 a.m.	Call to Order, Opening Remarks, and Introduction of the Committee	Panel Chair
9:05 a.m.	Conflict of Interest Statement	Candace Nalls Designated Federal Officer
	FDA Presentations	
9:15 a.m.	Device Classification	Ryan Ortega, Ph.D.
9:30 a.m.	FDA-Approved Computer-Aided Adjunctive Devices for Lesions Suspicious for Melanoma	Colin Kejing Chen, Ph.D.
9:50 a.m.	Post-Market Safety and Effectiveness	Henry Lee, M.D.
10:00 a.m.	Device Classification and Reclassification Overview	Neil R.P. Ogden
10:15 a.m.	Proposed Reclassification and Regulatory Controls	Neil R.P. Ogden Scott L. Kominsky, Ph.D.
10:25 a.m.	Clarifying Questions from the Panel	Panel Chair
	External Speaker Presentations	
11:00 a.m.	**Open Public Hearing*	
Noon	Lunch	
1:00 p.m.	Questions to the General and Plastic Surgery Devices Panel	Jianting Wang, Ph.D.
3:00 p.m.	Day 2 – Adjournment	