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510(k) Premarket Notification Database

Device Classification Name Nystagmograph

510(K) Number K972243 **Regulation Number** 882.1460

Device Name2D VOG - VIDEO-OCULOGRAPHY

SENSOMOTORIC

Applicant INSTRUMENTS, GMBH

Potsdamer Str. 18a

Teltow, GM 14513

Contact Annikki Persson

Classification Product Code GWN

 Date Received
 06/16/1997

 Decision Date
 09/10/1997

Decision Substantially Equivalent (SE)

Classification Advisory

Committee

Review Advisory Committee Neurology

Statement/Summary/Purged

Status

Summary/Purged 510(K)

SummarySummaryTypeTraditional

Reviewed By Third Party No Expedited Review No

Database Updated 10/04/2005