

K963593

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Premarket Notification of  
New Device  
THE LOUPE-COLOSCOPE  
Summary

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Approval is sought for this device with the intent of marketing it . It is truly felt that it is a very safe instrument for attendants to use for evaluations and aid to certain treatments. It is felt that it has distinct advantages over existing instruments that are presently available for such procedures because it is portable and self contained, since it has its own light source, green filter and variable magnification.

The testing done on this instrument was done safely and scientifically controlled; these showed that this Loupe -Colposcope is equal in performance and accuracy to standard operating microscopes. Because of its portability, it should be of great value in evaluating patients in remote areas, third world countries, and emergency situations. There were no adverse effects to patients when this instrument was used to examine them or assist in treatment procedures.

For the first sixty-one patients the following blinded control study was used. The examinations used to evaluate this instrument were blinded between the Loupe and the Zeiss OM-1 operating microscope operators and these operator colposcopic diagnoses were compared to Papanicolaou smear diagnoses and histological diagnoses from the ones taken during the testing procedures. The patient's colposcopic findings were also blinded to the pathologist.

Because the results of these sixty-one control cases showed excellent comparative results, the remainder of the case results were compared to Papanicolaou smear tests taken at the time of the examination and pathological results from biopsies taken at the time of the examination.